Transcript of:

PUBLIC MEETING SULFONAMIDE RESIDUES IN SWINE

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United States Department of Agriculture
Food Safety and Quality Service

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UNITED STATES DEPARTMENT OF AGRICULTURE

PUBLIC MEETING

SULFONAMIDE RESIDUES IN SWINE

U.S. Department of Agriculture
Conference Room B
Interdepartmental Auditorium
1301 Constitution Avenue, NW.
Washington, D.C.
10 a.m.
January 16, 1978

INTRODUCTORY REMARKS BY CAROL TUCKER FOREMAN,
ASSISTANT SECRETARY, FOOD AND CONSUMER SERVICES,
USDA

MRS. FOREMAN: Good morning. Thank you all very much for coming. It is certainly a rousing turn out for early Monday morning.

In the past several months, the Department of Agriculture has been receiving an increasing number of questions concerning our monitoring program for sulfa residues in swine, and I am sure the same thing is true of the Food and Drug Administration. These questions have indicated a great deal of general bewilderment, considerable consternation, and in some instances even outright anger on the part of swine producers.

It is a problem that we thought we could begin to approach most effectively by getting all of the interested parties together to discuss as many elements of the problem as we can.

First, today, we want to discuss the problem of how extensive the sulfa residues in swine are; second, we will outline the legal requirements on USDA and FDA in regard to sulfa; third, we would hope to give everyone an update on the current status of knowledge of this issue; fourth, by sharing knowledge and ideas I hope we can begin to open up some avenues to resolving the problem.

We are going to have to find solutions to the problem of violative sulfa residues in swine. Sulfa is obviously a very important drug in hog production. Its use as a feed additive increases the efficiency of production very substantially. Sulfa residues in hog meat, however, have public health implications that neither the law, nor in fact common sense, will allow us to ignore.

Surely we can all agree that production of abundant and low cost food cannot be achieved at the expense of public health safety. Food is to nourish the body. From the beginning of organized society, there have been efforts to keep the food supply safe and pure.

The USDA has a clear responsibility under the law to safeguard the food supply, and obviously we need to carry out that responsibility. We think that it is to the advantage of producers to maintain public confidence in the safety of the food supply. Raising pork efficiently will not do the producer any good if people are afraid to use pork products.

I am persuaded that we can have our cake and eat it too, that we can have a safe and abundant food supply. That is probably going to require some change on the part of all of us, but change after all is one of the most constant things in our lives. We all have to live with it. I think we can work together and by working together, we can resolve the sulfa residue problem.

We are committed, I assure you, to using the most conservative actions that will resolve the problem. The extent of our action will be no greater than the problem demands.

Dr. Angelotti will speak of some progress that has already been made in resolving the problem, and I hope today that you will be able to develop ideas and courses of action that will resolve the problem completely. Our country depends upon an agricultural community that is strong and productive, but it will remain strong and productive only if American consumers can be confident of the safety and quality of their food supply.

Thank you.

REMARKS BY DR. ROBERT ANGELOTTI, ADMINISTRATOR,
FOOD SAFETY AND QUALITY SERVICE, USDA

DR. ANGELOTTI: Thank you, Mrs. Foreman.

Let me welcome you all to this proceeding. We have with us today representatives from the several affected groups upon which this problem impacts. We have representatives from the several agencies of the Department of Agriculture which in one way or another contribute either directly or indirectly or may contribute directly or indirectly to the resolution of this problem, and we have our colleagues from the Food and Drug Administration with us.

I will spend just a moment or two outlining what it is we will attempt to do today and give you some information.

The difficulty that confronts us is that we are seeing residues of sulfa drugs in swine that exceed the FDA established tolerance. The adulteration provisions of the Meat Inspection Act state that any meat which contains a residue above tolerance is adulterated under the Act, and we thus are forced to take appropriate actions to prevent such adulterated meat from entering commerce. That is the crux of the problem from the legal point of view.

Now there appears to be some confusion not only among the people in the Department of Agriculture but also folks outside the Department, relative to the reason that this problem exists. Our records indicate that about 15 percent of the swine tissue samples that we examine are over tolerance. This has been a continuing problem for a couple of years.

There appears to be a trend now that may indicate the tolerance incidence, the incidence of excess tolerance, is being reduced. We have some information before us that is a compilation of data from November, I assume from October as well, indicating that the over-tolerance situation has moved from about 15 percent down to 10 percent. That is very

heartening, and we are pleased to have this information. However, that is not the end of the problem. We would like to see an elimination of the residue problem and get it down to the lowest possible incident rate that is achievable within the practicalities of the situation and in keeping with the public health practice.

We do not feel at the moment that everything has been done on our part that could be done; there are some remaining things that we could do. We are hesitant to do those because of the severe ramifications such actions would have, but let me point out to you some of the things that are yet to be done, if necessary.

We could institute a program of testing all lots of swine at slaughter. I think those of you who are in the business understand the severity of that action and the ramifications to you should that be taken.

A second thing that could be done would be to request the Food and Drug Administration to remove the sulfa from swine feed and remove their permitted use as water additives.

Now, we are not certain why this problem continues, and why it has continued for such a protracted period of time. The proceedings today hopefully will give us greater certainty as to what is the source of the problem.

We are hopeful of getting information from a very practical point of view relative to what happens on the farm, what the feed manufacturers may be able to tell us relative to the practical experience in feed mill operations, and we would like to hear the latest information coming out of certain research laboratories.

Part of the problem may relate to feed manufacturing technology in that cross-contamination may be the problem. It may be occurring at the feed mills, in that there are difficulties being experienced in cleaning feed mixers, delivery trucks, transport systems and the like.

The problem may rest to some measure with the farmer, who for one reason or another is having difficulty withdrawing the medicated feed on schedule. He may be suffering difficulties in cleaning the troughs and feeding materials that he uses in his individual farm, and he may have a problem as it relates to water contamination on his premises.

Lastly, the problem may in some way be related to environmental factors that aren't too well understood at the moment. Such things as carryover in feces, and running pigs over manure lots and the like may be part of the problem.

Now, the bottom line, of course, is what are we going to do about it? How can we see to it that the incidence of over-tolerance swine is

reduced even further than what appears to be a very heartening reduction that we have noted lately.

What do we need to do to be certain that the reduction carries forward into the future and is reduced even further, if possible? What is it the farmer can tell us that will be helpful to us? What is it the feed manufacturers and drug manufacturers can tell us that will be helpful? What is it that FDA can tell us that will be helpful? And, lastly, what is it those of us in the USDA know at the moment that may contribute to solutions, and what remains yet to be known and what do we need to do to get that kind of information?

That is what this meeting is about, and hopefully each of you making a contribution to these proceedings today will give us the kind of insights that will help us resolve the problem.

Now with that let me turn the microphone over to Dr. Van Houweling of the Food and Drug Administration, who will spend a moment or two discussing with you FDA's legal responsibilities in this activity, and then we will move on to a presentation by both USDA and FDA folks as to what the two agencies know about the problem at this point in time.

Dr. Van Houweling.

REMARKS BY DR. DONALD VAN HOUWELING, DIRECTOR
BUREAU OF VETERINARY MEDICINE, FDA

DR. VAN HOUWELING: Thank you, Bob. Secretary Foreman, and ladies and gentlemen, we are happy to be here at this meeting that you have called to see what we can contribute to the solution of the problem.

Dr. Kennedy, our Commissioner, hoped to be here. It developed that he couldn't be, and he wrote a memo suggesting that I take his place and also suggested that we have some knowledgeable people on the subject at the meeting as well. I brought several people along in case we have such detailed questions. I think I have got as back-up people knowledgeable on the subject to be able to help us out.

Dr. Cazier, of course, will be reporting in some detail a little bit later about some of our findings.

My topic is our regulatory responsibilities. It is really quite simple. I think, first, we have the responsibility to approve the use of animal drugs in food additives when a manufacturer gives us sufficient data that it is effective and safe, and after we have approved these products, on the basis of the data they have given us, if we later have questions about the safety of the approvals, or the use of the product that has been approved, we have the responsibility to do something about it.

So as far as the approvals and withdrawals are concerned, there really is no question--the responsibility lies with the Food and Drug Administration, and more specifically relating to our Bureau of Veterinary Medicine and Bureau of Food.

As I have said, to have things like withdrawal and tolerances with no program to monitor whether they are being followed, would really be nothing more than a paper exercise. So, for a good number of years we have had an agreement with the Meat and Poultry Inspection Service of the Department of Agriculture to do this monitoring. In fact, several years ago we developed a Memorandum of Understanding between the two agencies which describes in some detail how we will work at this together. I am sure USDA will be describing what their monitoring program consists of, the different phases of their monitoring program, but part of our Memorandum of Understanding and our agreement is that violative residues that they detect in their monitoring phase of their program are all reported to us.

This first slide speaks specifically to what our role is when we receive violative residues from Meat and Poultry Inspection.

First of all, the thing that we do immediately is to request the field offices to conduct an investigation, and when the premises can be discovered a complete investigation is carried out, whenever we can. As a result of the investigation, there are several things that we can do.

First of all, we do routinely provide a report or letter to the producer explaining what we have found and indicating the seriousness of the situation and urging their attention to the deficiencies.

Now, if there are repeated violations and there is an indication that the public is affected by the producer, we certainly are in position to write what we call a regulatory letter and begin to consider prosecution for having introduced in interstate commerce contaminated food.

Several years ago we got our General Counsel to interpret the act as saying animals destined for slaughter in a federally inspected slaughtering establishment can be considered food in interstate commerce. So we have the basis for prosecution if the circumstances seem to warrant it, and we are fully prepared to do so.

Now, in addition to actions against the producer, we also can take action against the approvals. If it is our conclusion that the approval was not proper, that for some reason or another the drug is not being used in the way it was meant to be used, in other words, if our label directions are such that producers are not able to follow them, we have some responsibility at least to modify the labeling, and that usually is our first approach.

As you know, in this case we have extended the withdrawal period to 15 days. That is one step that should be taken to help reduce the violative residues.

Now, if those actions are not sufficient, we can restrict the use to certain animals, certain species, say young animals, over a certain period of time before slaughter, and various restrictions of that kind. But if none of this seems to do the job we can, of course, give consideration to withdrawing the approval. When we do it, of course, we have to propose in the Federal Register to withdraw and provide an opportunity for a hearing on the part of the drug manufacturers and others who are affected.

I think, too, as Dr. Angelotti has already said, the bottom line on this particular subject is that unless the violative residues come down very substantially, and producers can show they can use the drug as currently approved, we will have to consider further restrictions on the use. Withdrawing the approval is also a possibility, because I think that USDA can't tolerate this percentage of violative residues or adulterated food that is in their inspected channels.

DR. ANGELOTTI: We will next have a presentation of the history of the sulfa problem with some discussion of insights that the Food Safety and Quality Service has gained as a result of our experience and a discussion of the methodology involved in making the determinations in our surveillance activity.

Dr. John Spaulding of our Meat and Poultry Inspection Program will make that presentation to you, and before John starts, let me excuse myself and Mrs. Foreman for just a moment or two. Hopefully, John, we will be back by the time you finish your presentation. If we are not, would you please carry on in my stead?

DR. SPAULDING: Yes sir.

REMARKS OF DR. JOHN SPAULDING, CHIEF STAFF OFFICER, RESIDUE EVALUATION AND PLANNING STAFF, MPI, FSQS, USDA

DR. SPAULDING: I feel my role today is to briefly present the information we have obtained from the sulfa residues in swine. I am speaking really for my staff because they have done the background work in talking with producers and working with industry to obtain this information.

I think the first and most important part is to place this problem in perspective.

As most of you should be aware, over the past 6 years there has been a serious residue problem with every animal species that is amenable to

the Meat Inspection Act or Poultry Inspection Act. This means that the pork industry is really not having a unique problem but rather a problem similar to what all other animal industries have faced and resolved.

We have learned from these previous experiences that there seems to be a series of events that we must go through.

Dick, if you will show the first slide, please.

There seems to be the set series of questions we must come to answer. We are always questioned about the bias of our monitoring program. Are we running a true monitoring program, or do we have some bias in it?

The next is the challenge to accuracy of our analyses and the analytical methods that we use.

The next is the question of the practicality of the tolerance levels under real life or farm conditions.

Finally, after the first three are resolved, and we have developed an interchange between ourselves and the industry, we get to the last and most important step, actual resolution of the problem.

What we have learned is that until we, the Federal agencies and the producer groups, actually start working together, these problems are very difficult to resolve and probably will last. You could say the first three are essential to developing enough mutual trust and respect in order to make the fourth work.

We have collected swine samples for sulfa residue analysis for all 48 continental States. The areas with 10 percent or higher residue violations appear to be markedly similar to the swine producing States.

The next slide.

Also there has been almost a pattern starting to show. As you can see, we started back in 1974 and the data is quarterly, and then in 1976 we started to step up the program and, finally, in 1977 we raised the program quite considerably.

In looking and asking our statisticians to do trends on this data, they tell us that the trends in lowering the incidence at any level you wished to measure--started back in September and October--and this is why it really took until November for us to see. It also explains why when we look at histographs we weren't able to pick it up because it was a decline across all levels of residues.

The other thing that we learned is that we have got to be extremely careful in interpretation of this data because, as you know, we are

down to 10 percent in November. That is approximately where we were a year ago.

Some people questioned why we raised the sampling rate so high in June. Did it have any effect? The answer is that it lowered the overall level for reasons that we cannot explain. That at June we had 95 percent of all residue results below eight-tenths of a part per million.

In July, that dropped to .4 parts per million, and it stayed at the .4 level since then.

Now, back in '76 we talked with FDA and said we were concerned. We talked with the swine industry leaders and informed them of our concern. At that time, FDA investigations indicated the primary problem was lack of careful use of the drugs at the farm level. I believe this has now changed. At least we have data indicating it is not always the farmer's fault.

Dr. Cazier will give further facts on their findings. Dr. Farber will discuss the tolerance-setting procedure. So I will now talk about analytical methods as we use them in our meat and poultry inspection laboratories.

This analytical procedure consists of four separate steps, which begin when the sample is collected. In the world of micro-analytical chemistry there is no truer saying than the analysis is no better than the sample being analyzed. Our entire residue program data are based on analysis of samples frozen quickly at the slaughter plant and kept frozen until ready for analysis.

Before any chemical analysis can begin, the chemists make sure the sample is suitable for analysis.

We also learned in this program on sulfonamides that the kidney-liver value reported in our program are about equal. Muscle valves are about one-half of that value. Therefore, we analyze liver tissue first, then go directly to muscle if we have a violation.

Dick, next slide.

The first step is thin layer chromatography. We spot standards on the plate. If the values when we spot the unknown are below what we consider to be a tenth of a part per million equivalency, we call the step negative. In other words, we report it as ND. That is where 85 percent of our samples have been stopping during the past 4 years.

If they are considered to be equal to or above a tenth of a part per million, then we go on to the next step.

This is the GLC step in which we make a metal derivative of suspect sulfa and we inject it. Then we have a peak that has got to be characteristic of the compound, and the peak again has got to be a sufficient height to indicate a tenth of a part per million, or in that range, or more is present, or we stop the analysis at that point and report the sample ND.

By the use of standards and standard retention times on GLC we can identify most of the sulfas commonly used.

Needless to say, in this case we are talking about sulfamethazine. So naturally we always use a sulfamethazine standard on the LC plate. We know precisely the retention time of sulfamethazine in our GLC.

Next slide.

If these two are positive, still indicative of a violation, we go to the Tischler procedure. Parts of the clean up in all these steps in the wet chemistry removes most interfering compounds, and when we remove these compounds then we know that we have got a sulfonamide drug present. This makes the Tischler procedure extremely reliable from a quantitation standpoint.

This then gives us the final quantitation, which means that all this does is tell us what we already know, and it gives a finite number.

Now, this is the analytical procedure. I have gone through it fast but I want to speak of one thing about this analytical procedure. In order to run a residue program, there are requirements placed on the analytical procedures that we use.

First, we can only use analytical methods for final reporting of violations that have been approved by the Food and Drug Administration. Prior to that, it is the responsibility of the drug companies that market these drugs to furnish to the Food and Drug Administration and thereby to us, analytical procedures that are suitable for regulatory control. These procedures and the sequence of events that meat and poultry inspection has developed, and is the only one they have used out of literature, is the Tischler procedure. This is recognized by FDA as being the correct procedure. FDA and the drug industry has known we have been using these procedures for at least 5 or 6 years. They have also been with us on problems of sulfonamide residues with other industries, and they have not suggested that we change what we are doing.

Other analyses in the private laboratories--and most of you do know that we exchange samples with private laboratories--are using exactly the same procedures. Private labs have suggested deviations, variations of the procedures, but the basic procedures have stood up.

I hope I have convinced you that we are using the current available best technology on analytical procedures.

In regard to the other facts that we have learned during the first 18 months about this problem, we are aware that obtaining medicated-free feed is a major problem for swine producers. Based on food analysis supplied to us by producers, and analytical results on tissue, we estimate that it takes a withdrawal feed below 1 part per million to produce in compliance animals, and anything over 5 parts per million will produce violations.

Dr. Bevill hopefully has a little more precise data on that. The Extension Service provided data that indicated environmental contamination could be an important factor. Swine producers helped convince us of this fact. Due to the hog procurement practices of a major swine slaughterer on the west coast, our data indicate that given clean feed and surroundings the stated withdrawal period should be adequate. The catch is meeting both of these conditions on a hog farm. Naturally there has been an occasional residue occurence that did not seem to be possible based on available facts. Given the multiplicity of possible causes and sources, it is a wonder there have been so few.

In fact, today it would be much easier to explain a higher violation rate than it is to explain why we have had slightly more than a 90 percent compliance rate in November.

The graph I showed you indicates the dropoff, and hopefully this change is something we can build on.

In conclusion, let me reemphasize this has been a longstanding problem. The causes appear to be multiple. We must all work as a team to correct the problem. Through the help of research and producers we should be able to pinpoint what needs to be done in the future. We will take action to assure that every producer is furnished the information he needs to produce swine that do not have violative levels of sulfa in tissue, but we need to know what to tell him.

Evidently since 85 percent of the producers have been doing it right, the facts must be out there if we can just put them together.

Our next speaker is Dr. Victor Berry. He is in charge of our field operations and will speak about the operation of the field program which also has been of concern in some questions.

Vic?

REMARKS OF DR. V. H. BERRY, ASSISTANT DEPUTY ADMINISTRATOR FOR FIELD OPERATIONS, MPI, FSQS, USDA

DR. BERRY: I would like to talk about our present system and give a summary of the actions that we have taken in regard to sulfa residues in 1977.

As mentioned earlier, we see a responsibility of seeing to it that those animals or birds which have violative levels of residues do not reach the consuming public. The field surveillance program is just one of the vehicles by which we direct our available resources toward meeting this responsibility.

I would like to emphasize that our actions in the field, regulatory actions, are simply one of the methods by which we try to meet this responsibility.

First, let me talk a little bit about the system. There are essentially two phases to our residue program. The first is a monitoring or objective sampling phase.

At the national level a sampling schedule is put together which details or gives the plants in which the animals or birds are produced. That schedule then is sent to the field. Along with the plants from which the samples are to be taken, it also details the number of samples to be taken. It relates to the production in plants in terms of numbers of samples.

The last slide is the actual taking of the sample or selection of the sample by the inspector in charge in the plant that we are talking about.

This is done randomly on a so-called time basis. In other words, the fellow that morning selects at different times during the day that he will randomly take a sample. That sample is prepared and sent to the laboratory. Now, depending upon the laboratory determination, the decision point is there. If the sample in the case of sulfa is in compliance, then there is no additional task required.

In other words, that number simply goes into our national monitoring statistics. If it is out of compliance, that sets in motion our so-called surveillance or selective phase of sampling.

The region that is involved is notified of the violation. The producer is notified both by telephone and by mail. At that point the selective sampling begins. In other words, livestock coming from that particular producer is then subjected to either pretest or holding for a period of time for sampling within the plant.

After the sampling begins, of course, the samples are sent to laboratories, either approved laboratories of the producer's choosing or to the FSQS laboratories.

Again, a determination is made on a number of animals, and if they are in compliance the producer returns, as we say there, to the objective phase of sampling, but that he goes back into the large pool of random sampling.

If the sample is not in compliance on a representative sample of his animals, then we return essentially to step 2 with further restrictions on the slaughter of those animals.

Let me show now a sort of geographic picture. This is kind of a busy slide, but let me see if I can't make some sense out of it.

We have divided the United States into five regions. The north central region contains the States of Illinois, Indiana, Iowa, Michigan, Minnesota, Nebraska, Ohio, and Wisconsin.

The thing that slide is showing up there is that the overwhelming share of the problem is in the north central region. The largest number of hogs, of course, are produced there, and indeed the largest number of hogs are slaughtered in the north central region.

The largest number of samples come from the north central region, and indeed the largest number of violations by percentage come from the north central region.

Approximately 68 percent of the sulfa samples in 1977 were collected in the north central region, and approximately 71 percent of all the violations were found in this grouping of States. This particular grouping of States had 702 actual violative cases, of which 446 were closed. Closed means they were traced to the producer.

A series of pretests or inplant samplings were carried out, and the problem corrected on those from that particular producer. Of the 702, approximately 256 are cases that are still open.

I think that summarizes the regulatory or surveillance actions that we have carried out in the field in 1977.

Thank you.

DR. SPAULDING: (Presiding.) Thank you, Vic.

The next speaker is Dr. Phillip Cazier, and he will speak about the findings of the FDA field investigations and a little bit about withdrawal periods.

Phil?

REMARKS OF DR. PHILIP CAZIER, ACTING ASSOCIATE DIRECTOR FOR SURVEILLANCE AND COMPLIANCE, BUREAU OF VETERINARY SERVICES, FDA

DR. CAZIER: There is not a great deal to say right at present about withdrawals periods. I think you are all well aware that in October we sent out a request to the drug pre-mix manufacturers to extend their withdrawal period to 15 days. We also asked producer associations to observe this withdrawal period in advance of the changes. We asked the feed manufacturers on a voluntary basis to change their feed labels to show a 15 day withdrawal period.

Recently, I had my staff go through 296 memorandums of origin investigation reports. These are the reports that are written by the Food and Drug inspectors when they go out to the swine producers' premises to attempt to find out the cause of the residue. They went through these reports closely and in detail to get as much information from them as they could.

Out of the 286 reports that they went through, they were able to identify the producer in 86 percent of the reports. Then they looked to see what the probable cause was. Out of these 247 reports, they were able to determine from the report the probable cause in 70 percent of those reports.

There are several cause categories here. Withdrawal periods not observed was 25 and 2/10ths percent. Probable contamination of the withdrawal feed with sulfonamide through various means, such as carry-over-from mixing equipment, feeders not cleaned, trucks possibly not cleaned amounted to 57 percent. This is a little change from what we have observed previously.

In most of our reviews of the inspection reports we find the withdrawal period not being observed is usually the major cause. They have a category here of accidents such as the pigs breaking out; inadvertant mixing of pigs, unintentional errors of one kind or another, which amount to 11.8 percent.

Unapproved use of the drug, was 1.8 percent and probable contamination of a watering system sulfonamide would be .8 percent.

We have one other category, feces and urine recycling, which is 2.4 percent. I do not place any credence in that figure. It happened to be some observation they made from the inspection reports which indicated that there was quite a buildup of the manure packs, and it is a very subjective figure.

I think the two that are the most important and of interest are the withdrawal period not being observed and the contamination of the withdrawal feed.

They broke out the withdrawal not observed into two categories--intentional or through producer negligence, 17.6; unintentional, 7.6.

They broke out the contamination of the withdrawal feed into two categories; one, mill related, 8.8; producer related, 48.2.

They attempted to determine where the feed was mixed, whether it was on a farm or in the commercial mill. Out of 212 reports, from which they could do, 138 were mixed on the farm, 74 at a commercial mill.

They looked at whether they could determine if mixing equipment had been cleaned, medicated and non-medicated feed, and nine of those reports indicated that they had been cleaned, 93 were categorized no, they had not been flushed or cleaned.

Another question that they looked at was feeder cleaning when switching from medicated to non-medicated feed. Yes, was 7, no was 66.

Water medication was implicated in only two cases.

Thank you.

DR. ANGELOTTI: (Presiding.) Thank you, Doctor Cazier.

Next on the program is Dr. Ted Farber from the Division of Toxicology of the Food and Drug Administration. Dr. Farber will speak to us about the tolerances and manner in which the tolerances for these drugs are established, something about the toxicology of the drug and the human health significance of the tolerance and over-tolerance.

Ted?

REMARKS OF DR. TED FARBER, CHIEF,
FOOD ANIMAL ADDITIVES EVALUATION BRANCH,
DIVISION OF TOXICOLOGY, FDA

DR. FARBER: Thank you.

At the time the Bratton-Marshall method was adopted for measuring levels of sulfa drugs in tissue, no toxicological information of the type currently recognized as a minimum standard was available to support a 0.1 per million tolerance as being adequate to protect human health. However, at that time, it was reasoned that because there had been some 20 years of human clinical experience, 0.1 parts per million or less should not be a hazard to human beings when consumed on an occasional basis.

I would like to emphasize the occasional aspect of exposure.

At that time, sulfonamides were used in veterinary medicine primarily as therapeutic agents, so exposure was intermittent and there was usually a long withdrawal period following medication.

Thus, very few animals would have residues even approaching 0.1 parts per million.

However, with current swine management programs, very large numbers of animals are given sulfonamides continuously throughout their growth and fattening periods.

In 1969, the Food and Drug Administration received some toxicological information regarding possible thyroid changes associated with the administration of sulfa drugs. These findings, supported by the change in the use pattern of sulfonamides over the years, necessitated requests by Food and Drug Administration for additional toxicological data on sulfonamides.

In response to a Federal Register announcement in 1973, manufacturers of sulfonamides have provided the requested toxicity data to support the safety of most sulfa drugs.

While the original setting of the tolerance at 0.1 parts per million was arbitrarily based upon our pharmacological judgment, we now have data from traditional animal studies that shows that our judgment was accurate.

The sulfonamide toxicity data supports a total residue in tissue of 0.1 parts per million as being toxicologically insignificant. For some sulfa drugs the acceptable mark of safety used for a negligible tolerance of 0.1 parts per million is just barely met, but it is met. Such is the case with sulfamethazine. A few sulfonamides even at a level of 0.1 parts per million have a toxicity that is too high, and we have taken steps to require more sensitive assays or additional toxicity data.

The agencies should like to point out that the toxicity data submitted on sulfa drugs are only 90-day studies in dogs and rats, which are the minimum data acceptable to support the 0.1 parts per million of residue in tissues. For higher tolerance we would require as a minimum lifetime studies in two rodent species, a three generation reproduction study, and at least a 1 year study in a nonrodent species such as the dog.

The latest, and we believe to be the most comprehensive toxicological studies funded by the Animal Health Institute, shows no effect level of two milligrams per kilo of body weight in the rat and dog in the 90-day studies for sulfamethazine.

If we apply our traditional 2000-fold safety factor, a safety factor derived from the deliberations of the Committee of the National Academy of Sciences, we arrive at a tissue tolerance of 0.1 parts per million as the maximum safe level for sulfamethazine in man.

The toxicological data we have on hand currently will not support a tolerance higher than 0.1 parts per million for sulfamethazine.

It has been suggested by some individuals in the swine industry that the tolerance for swine kidney and liver be raised to a level of 0.3 parts per million so that many of the above tolerance carcasses will pass inspection.

The agency has modified its guidelines recently and allows an upward adjustment on the tolerance of edible tissues which are not consumed as frequently as muscle. However, the levels of residue in muscle must be considerably below 0.1 parts per million before this adjustment is made.

Regrettably, data from the meat and poultry industry in special residue program indicates that 0.13 parts per million of residue in liver and kidney tissue will be related to a significant number of muscle residues above 0.1 parts per million.

In fact, when total tissue violations are considered, a 10 percent reduction might be all that is realized in the proposed increase for the tolerance for liver and kidney tissue.

For the above reasons, at the present moment we are reluctant to make any changes in the tolerance.

Thank you.

DR. ANGELOTTI: Thank you, Dr. Farber.

We will now hear from a group of research people who have been working in this area and who will relate to us some of the more recent findings which hopefully will lead us to a better understanding of the problem. We have reserved time on the problem for a series of questions and answers immediately following the research presentations and prior to our lunch break.

Our first speaker in this area is Dr. Richard Bevill who is Associate Professor or Veterinary Pharmacology and Toxicology at the University of Illinois.

REMARKS OF DR. RICHARD BEVILL, ASSOCIATE PROFESSOR, VETERINARY PHARMACOLOGY AND TOXICOLOGY, UNIVERSITY OF ILLINOIS

DR. BEVILL: The work that I would like to report on today really was completed essentially since last June, but actually these studies were begun 5 years ago with extramural funding provided by the Bureau of Veterinary Medicine.

When we first started working on this everyone wanted to know why we were working with sulfonamides, and I think last summer they found out why.

If I could have the first slide.

This first slide shows the basic nucleus of that contract that we worked on for FDA, and it really was to determine whether we could use plasma concentration as legitimate predictors of the existence of tissue concentration of sulfonamides.

The dotted line on this slide indicates the decay of sulfamethazine, in this case in plasma.

The solid lines are different tissues, including heart, muscle, liver, kidney, two types of fat, muscle sample at three sites. You will notice there is a parallelism at three sites, and a parallelism in the fall of the drug in the tissues and in plasma.

If we look at the next slide you will see that there is a great correlation between the concentration of the drug in tissues which is plotted on the vertical axis and the plasma concentration of the drug plotted on the horizontal axis.

These correlations ran from .99 to 1.

As you know, one is a perfect correlation.

In order to really make hay with these findings, we knew the method with which we could determine a tenth part per million sulfamethazine in plasma. That is the next thing we set out to do and by last June, we had completed this method.

It would be helpful if we could dim the lights. This slide will not show up without the lights off. But this is the method for the determination of sulfas in plasma.

And, from the left side of the slide we have zero parts per million, in the first two lanes, then a tenth, two-tenths, four-tenths, eight-tenths, and 1.6 parts per million.

Now, this is not very helpful unless we can quantitate it. People want hard numbers. So what we do is scan this with an instrument known as a benzatometer. If I could have the next slide, please.

You will notice that we get record peaks. The first peak which is labeled in each instance is due to an internal standard which we had was sulfamethazine absorbed, little used in swine, and we felt this would be a very useful internal, standard. It gives us a little better means of quantitating.

You will notice (a) is 0.0 parts per million; (b), a tenth; (c), two-tenths; (d), four-tenths; (e), eight-tenths; and (f), 1.6 parts per million peaks.

So this proved to be a very effective method for monitoring very low concentrations of the drug and plasma, which we highly correlated with coexisting concentrations in tissue.

Now, we had a lot of problems with producers who said we are following withdrawal but have problems. The plasma method gave us a very excellent means of following the problem on the farm and an ability to assess corrections made on the farm.

If I could have the next slide, please.

Now, we went to a major midwestern packer, last March, after we had the plasma working, and we asked if we could sample hogs at slaughter. We essentially identified groups of five animals coming from every lot of animals supplied to him on that day. At that time we did the plasma tissue concentration on sulfamethazine. This was kidney tissue which we sampled. And at that time 33 percent of the animals down the line had some sulfamethazine in them, 21 percent of the animals were in violation. There was essentially a factor of 2.5--for every 2.5 parts per million of the drug in the kidney of plasma we found 1 part per million in the kidney.

The correlation was .92--still very good. And so we felt that we had a very positive correlation between the concentration of the drug in plasma and those present in tissues.

We conducted three studies last summer which I think are quite important. At first we wanted to know what is the minimum concentration of drug in feed which will produce violative tissue residue.

Could I have the next slide, please?

DR. ANGELOTTI: Is that a linear regression?

DR. BEVILL: That is a linear regression, yes.

The concentration of sulfamethazine in the ration feed to groups of three animals is presented on the lower part of the slide. You will notice 2 parts per million, 4 parts per million, and 8 parts per million. Concentration of sulfamethazine in parts per million in various tissues is plotted on the vertical axis.

We fed sulfamethazine at 2, 4, and 8 parts per million, containing three pigs each for one week.

We sampled plasma, liver, kidney, and muscle, and essentially what we found at these low levels was that at 2 parts per million there was more than a tenth part per million in plasma, on the average, and the concentration of the drug in liver exceeded the tenth part per million but was below a tenth part per million in kidney and muscle tissue.

However, these animals would have been in violation. So, at 2 parts per million you will get violative tissue residues in liver, the same goes at 4 parts per million, but at 8 parts per million, you are going to have violative tissue level or concentrations in all tissues.

Now this was significant because if you leave 40 pounds of feed that contained 100 parts per million of sulfamethazine in this case, you would have enough sulfonamides there to contaminate a ton of perfectly clean feed at 2 parts per million.

Next slide.

One of the questions raised was whether sulfamethazine misbehaves over long-term feeding. We feed 100 parts per million, which is the common use level of this drug for growth promotion purposes, for two weeks. Again the concentration in plasma plateaued at the end of 2 weeks. We discontinued the drug and feed and furnished the animals with a perfectly clean ration.

We followed the disappearance of the drug from plasma. As you can see on the plate it is linear, which means it is having perfect definite unit of time. The half light is 17 hours, which is very similar to that of an intravenous study.

We concluded sulfamethazine's 7 day withdrawal would be adequate because at 120 hours, or 5 days, we sacrificed these animals.

If I could have the next slide, please.

You will notice that the plasma was slightly below a tenth part per million, liver was right at a tenth part per million, and muscle and kidneys were below. This is at 5 days and not 7.

Now, last winter we were working with the producer, and we found that during the very cold weather that his sulfonamide residue problem seemed to disappear. In the spring it came back to haunt him. He has had a tremendous problem, and he has done everything he knows how to do or had up until summer to get rid of the problem.

We began to think about the possibility that this man was feeding on a concrete floor, that the urine and feces could be freezing, the animals would not be browsing them quite as much, and this could perhaps be a source of sulfamethazine contamination.

So this summer we also did a series of studies in which we set up two pens of animals. We fed one clean feed and one treated feed. There were six animals in each pen. At the end of 2 weeks we shifted pens. We put three animals from the treated pen in the clean pen and three animals from the clean pen in the treated pen. At that time we furnished a sulfonamide free ration to all animals.

Next slide, please.

You will notice the open circles are the treated animals which came off of the manure pack into the clean pen and received sulfonamide free ration.

Again, there was a very linear drop in the concentration of the drug in plasma. These animals would have cleared by the fifth withdrawal day.

However, notice the untreated pens which were placed on manure pack. These are start circles. Immediately within 2 days, we had concentrations in plasma which would have indicated that these drugs would have had violative tissue residues and these fell very slowly over the next 14 days, at which time we scraped the pen floors, and they fell even after that.

Now, since we didn't get completely rid of the drug, in the days between 14 and 21, we decided these pens should be washed, scraping would not be good enough.

Now we also looked at the solid dots, and these treated pigs that were left on manure pack. Notice that the levels fell very rapidly at first, and then they essentially came to the line that was described as treated pigs. They are receiving essentially the same amount of drug from the manure pack. You would expect them to fall in a very similar manner and they did.

It would appear that lengthening the drug withdrawal period is not a way to whip the problem. It would appear rather that we need to eliminate the source of sulfonamide contamination in the environment of swine.

Thank you.

DR. ANGELOTTI: Our next speaker is Dr. Richard Teske, Director of Veterinary Research with the Food and Drug Administration.

REMARKS OF DR. RICHARD TESKE, DIRECTOR OF VETERINARY RESEARCH, FDA

DR. TESKE: Thank you, Dr. Angelotti and Secretary Foreman.

As Dr. Bevill mentioned, we in the Bureau of Veterinary Medicine have been interested in this problem of sulfonamide drug usage for some time. May I have the first slide, please.

In 1975, we had done some work with sulfamethazine in turkey poults, and we had gotten a hint at that time of the kind of problem that we now face.

You will note that these were turkey poults that were receiving sulfamethazine in the drinking water for 6 days, and you will also note that the depletion pattern is comparable to those that Dr. Bevill just showed. It is very steep--until you reach about 3, .1 to .3 parts per million, and at that time it plateaued and seems to fluctuate.

At that time, we did not know what the cause of this problem was. We considered the possibility of binding in the tissues as well as recycling as a cause.

Next slide, please.

More recently we conducted a study using sulfamethazine in swine. The primary objective of the study was to determine what the effects of overdosage of sulfamethazine in the ration would be. The dosage level utilized 500 grams per ton.

This slide represents the study design in which we had essentially three groups of animals--a control group consisting of five animals which received sulfamethazine free feed, a group that was consisting of 21 animals divided into four pens that received medicated feed at a dosage level of 500 grams per ton for 30 days, and a third group consisting of six animals that had received no sulfamethazine containing feed. They were placed in one of the pens which had contained medicated animals at the time of withdrawal of medicated feed. They remained in that pen for either 6 or 15 days.

Next slide, please.

These are the withdrawal tissue levels from the 21 pigs that were medicated. Each number represents a sampling of three pigs, sampled at zero withdraw day, two, four, six and eight.

Keep in mind that these are pigs receiving a ration containing sulfamethazine at 500 grams per ton, or five times the recommended level.

You will note that the levels at zero day of withdrawal are quite high, representing roughly 30 parts per million in the plasma, down to 18 and 16 parts per million in the liver and kidney, with the lowest level appearing in the fat at 4.9 parts per million.

Significantly, on this slide are the levels present at 8 days, which show that the levels are essentially at the withdrawal, at the tolerance level or below after 8 days. This demonstrates that overdosage at least to a level five times that recommended will not significantly affect the depletion pattern of sulfamethazine in swine.

Next slide, please.

This slide is a little bit turned around. But basically, what we have here are the levels that were present in the bedding of the animals receiving 500 grams per ton. The pens are controlled pens on the right side. As one would hope, there was no detectable sulfamethazine present in the bedding from those pens.

Among the four treated pens, however,--and this is after 30 days at 500 grams per ton--the levels ranged from 125 to 350 parts per million in the bedding of those pens.

Next slide, please.

These are tissue levels from the previously unmedicated animals placed in those pens, one of the pens from which medicated pigs have been removed. Again we have the first column of numbers there from the control animals, representing zero levels of sulfamethazine present. However, after 6 days on the manure pack the levels were already violative in all tissues except muscle.

After 15 days they are violative--or that is not quite the right way to say it--the levels were significant and still rising after 15 days on the manure pack.

Next slide, please.

This slide represents or demonstrates the primary source of the sulfamethazine levels in the bedding, that urine levels from the medicated pigs--or 82 parts per million at the zero day withdrawal--depleted to 7 parts per million after 8 days of withdrawal.

This would indicate that simply cleaning the pens at time of withdrawal does not eliminate the contamination of the pen. We would still continue to eliminate significant levels for several days following withdrawal of the feed.

Among the pigs that were placed on manure pack after withdrawal of feed, we will note that urine levels reached a high of 20 parts per million among the previously unmedicated pigs placed on manure packs for 15 days.

Next slide, please.

In conclusion, we can draw these conclusions from this study. First of all, the depletion of sulfamethazine from swine tissues appears to be unaffected at five times the recommended level.

Second, feeding swine at 500 grams per ton does result in contamination of bedding with sulfamethazine at significant levels.

And thirdly, the bedding contaminated by swine fed at 500 grams per ton of sulfamethazine can result in violative residues in edible swine tissues.

DR. ANGELOTTI: Your next speaker is Dr. Gene Lloyd, Professor of Animal Pathology at Iowa State University.

Dr. Lloyd.

REMARKS OF DR. GENE LLOYD, PROFESSOR, PATHOLOGY,
IOWA STATE UNIVERSITY

DR. LLOYD. Thank you, Dr. Cazier.

Ladies and gentlemen, I have chosen to show you some data which may appear to be somewhat historical, but I believe they do seem applicable in today's dilemma.

Moreover, what seemed to be a dilemma at that time seems to fit the picture at this time.

Could I have the first slide, please.

These are data from a so-called classical toxicology study. I call it sub-chronic, better known as subacute study, in which the dose levels in this study were 70 milligrams of body weight, which is about one-half of the normal therapeutic level in animals.

The second dosage level is 2 milligrams per kilogram of body weight, which was a designated no effect level to obtain the 2,000-fold safety factor.

And of course, the inevitable controls--these studies were done in dogs and rats, both males and females. Our results indicated that there were no apparent effects at any level in dogs, and with rats there were some effects.

Next slide, please.

I apologize for a rather busy slide, but I thought this interested group would see through it.

First, this is rat's. It is the result of a "T" test comparing one level to another level. We see in the case of body weight there was no significant difference between the control levels and the low levels.

Now, in the second row we see that there is a significant difference between control levels and high levels. In other words, there was a growth depression.

There was also growth depression in considering the low levels, which is 2 milligrams per kilogram of body weight in the high level, or 70 milligrams per kilogram of body weight.

Those were all in females and males--somewhat the same picture but not as drastic. The rats went ahead and gained in spite of it, except the very high level.

You see there was a moderately significant difference between high levels and controls. No other significance in any other levels.

Now we are looking for goitrogenic activity. Ironically, in this particular case, all we saw was a decrease in thyroid weights in males between control and high levels which could very well be explained by virtue of the fact that they had not gained.

So, I doubt that this is a truly significant change when you compare body weights.

We did see an effect with bone marrow. There was a depression of the myeloid or granular sitis in comparing control versus high, and in this case, the males and females were considered together. So there was a significant change in that area.

Next slide, please.

Again, some historical data. However, it shows some differences between cattle and swine. In this case, all of these animals were from tests ascertaining the depletion curve after animals were given therapeutic levels to try to find out what level or what number of days withdrawal we should have.

These are animals that were not given any sulfonamides but were along with animals that did get sulfonamides, and we see a distinct species difference.

In this case, I would like to say that we were not able to use the Tischler at that time or this time to this great an extent, but these

were merely read by the chemist and these do illustrate a difference in the kidney. We see background levels of .009 parts per million.

Carrying over to the right, the same or respective levels of swine was actually a violative level, .1 part per million.

In the liver we had something very similar in cattle. We had a level of 0.017 parts per million, and in swine barely a level of .1 per million. In muscle, they were both below what we call actual level. You see, they were three times the levels. I call them background in swine as compared to cattle.

Now, your question comes to mind, is the so-called background level in cattle due to sulfonamides? I doubt it. In the case of swine, are the background levels due to sulfonamides? I don't know but I think they probably are.

Next slide, please.

In comparing the animals that actually did get sulfamethazine at therapeutic levels, we see in this case taking kidney on the seventh day in less than acceptable levels, and these are means of free animals in the case of cattle.

In the case of swine, they were much above tolerance--.36 parts per million--and these are means of six animals.

Day eight, cattle are below tolerance, and swine were still above tolerance.

After the first test, we called the Bureau of Foods and we called the research arm of the Food and Drug Administration, Bureau of Veterinary Medicine, and we said, "what do we do here, what is wrong?" They said, "do it again." So we did it twice, and we did it three times. That is, in swine. And you follow this on down and you will see that it, too, even at 11 days, in our studies, at 11 days, we still weren't below tolerance in either kidney or liver, that is swine, and we were in the case of muscle.

The only difference was that our pigs were housed on concrete, just like they are in a lot of Southwest Iowa farms. In Beltsville, they were housed on slats.

Next slide, please.

These are some data that were loaned to me by Dr. Clinton Paulson of the Wisconsin Department of Agriculture, and they are rather recent. They analyzed feeds that were supposedly ostensibly sulfonamide free, and these include premixes, complete feeds, and concentrates.

He found that 30 of these contained sulfamethazine but less than 1 part per million. Fourteen contained 1 to 5 parts per million. Eight of these were concentrates and six were complete feeds.

Two contained sulfamethazine at 5 to 10 parts per million. One of those was premix, and one a complete feed, and four contained sulfamethazine between 10 and 30 parts per million. One was a premix and three were concentrates. And three had 30 to 52.8 parts per million, which is the highest we found, and all three of those were concentrates.

Now, we found in our research that our mixer would contain about 90 to 100 pounds of medicated feed after it was empty. So that is one problem of mixing on the farm. This I think is another problem that the feed industry probably has to face up to.

Next slide, please.

This is an update of what we were doing at Iowa State University. We started out with 45 pigs, and this research is being supported by the National Pork Producers Council and also the ARS of the USDA.

We started out with 45 pigs, and we ended up with 35. We vowed we would keep them drug free and we did, but we paid the price. It is very difficult to raise a drug free pig in a confined environment.

We went ahead with the protocol, and we do have eight pigs that were just slaughtered last week, feed 110 parts per million, eight fed 11 parts per million. I guess there are only seven fed 11 parts per million, eight fed 1.1, eight fed no sulfamethazine, and we only had three which were really double controls, and it is our hope to extrapolate and project that a straight line dose/response relationship will pinpoint what level of feed we will give what level in the tissues.

I postulate it that there is about a 10 to 1 ratio, Dr. Bevill indicates, as of today. This is partly due to some mistakes I saw in industry where we were feeding 1 part per million, and we did get acceptable levels in muscle.

One significant thing, these pens were washed three times a day. The tissue are being analyzed now by the Meat and Poultry Inspection Service. They are being analyzed by the Food and Drug Administration and by Wolf, and Dr. Bevill is colloborating. So we do have good validation.

Next slide, please.

This is the last slide. This is some proposed research. According to the protocol, we wonder if this is going to be as meaningful as to how many times we wash the pens. In other words, we were trying to project what so-called therapeutic levels in rations would do at 7 days and feed 7 days and feed for 28 days.

Now, I don't think that is important as to how many times we clean the pens.

DR. ANGELOTTI: Thank you, doctor.

At this point on the program, we have provided an opportunity for dialogue, particularly questions that you in the audience and those of us up front might have of the research people relative to the findings that have been reported to you. However, you should look upon this opportunity as your chance to ask any of the speakers who made a presentation thus far any questions that you might have.

Based on what I have just heard, it appears that we may have more answers at this point than I thought we did. The research data indicates to me that we have multiple problems. We do have a problem related to environmental contamination on the farm as a result of manure pack and bedding.

We have a problem both on the farm and at the feed mill of residue within the hoppers and mixers and so forth resulting in contamination of supposedly nonmedicated feeds.

The last presentation indicates, particularly, that cleaning of pens on some periodic basis may have a beneficial effect in reducing the residue problem. We will have to await the further developments of that research to determine the optimal cleaning cycle for the pig pen.

I would be interested at this point in any comments that those of you may have that relate to practical considerations in view of these research data that we have just heard about.

How practical is raising hogs not on manure pack? How practical is periodic cleaning of all hoppers, mixers, troughs, and so forth, and how practical is a different bedding change schedule and pen cleaning schedule than now currently used?

We have placed microphones in the aisle. We have people located in the aisles who will carry the microphone to you in your seats, so you don't have to get up. If you have gotton up, that is fine. But the reason I am making the point is that my own experience is that it is very difficult to wiggle one's way out of his chair and across the aisle to get to one of the microphones.

Those of you who would like to comment just raise your hand and our people will bring the microphone to you in your seat.

Would you kindly state your name and your affiliation so we can get it into the record, please.

REPRESENTATIVE BEDELL: Yes, can you hear me? I am Congressman Bedell, and my question is to Dr. Farber. I am not sure I understood him correctly. Did I understand him to say that as far as the tolerance levels on liver and kidney were concerned, that the reason they didn't feel they should change it, they thought it would not help solve the problem for the pork producer?

DR. FARBER: No, I think that is only in part.

REPRESENTATIVE BEDELL: Did you say that or not? I thought I heard you say it.

DR. FARBER: I don't believe I indicated . . .

REPRESENTATIVE BEDELL: You didn't mean it anyway?

DR. FARBER: Let me clarify.

The adjustment of tolerance that we have recently put into action in the Bureau of Foods is dependent upon evidence that there is a significant--there is a level of residue in muscle tissue that is significantly below .1 part per million. This is not the case with sulfamethazine. At levels of let's say .2 parts per million or .3 parts per million in liver and kidney, any tissue, the levels of sulfamethazine in muscle in many of these situations is at least .1 part per million or maybe even higher.

So that in this particular situation, on sulfamethazine, it doesn't qualify for consideration under our present guidelines of adjustments on edible tissue such as liver and kidney, which is not consumed to as great an extent as muscle by the general public.

REPRESENTATIVE BEDELL: I am just a Congressman and don't understand some of this talk.

Are you telling me that the reason that you are not increasing the level for liver and kidney is that you think it would pose a dangerous health hazard to do so, or are you telling me that the reason you are not increasing it is because you think increasing it would still leave dangerous levels at the tissue point?

DR. FARBER: Well, our traditional way of looking at what we consider to be a level of toxicological insignificance is such that the level of the .1 part per million is considered, well, a level above .1 part per million based upon the kind of studies that we have seen coming in from industry. We cannot make a judgment that this residue is safe.

REPRESENTATIVE BEDELL: Is that on tissues?

DR. FARBER: Above .1 part per million.

REPRESENTATIVE BEDELL: On tissues or liver and kidneys?

DR. FARBER: What I am trying to indicate is that because liver and kidney of the swine is not a tissue that is normally consumed everyday by the average person in the population, if the level in muscle was significantly less than .1 part per million, there could be a tradeoff in essence.

REPRESENTATIVE BEDELL: You see, I don't understand.

DR. FARBER: This is not the case . . .

REPRESENTATIVE BEDELL: I don't understand the tradeoff. It seems to me if your concern is the tissue, which is the major item of consumption, than if the kidney and liver are minor items of consumption, I can't understand if you rate it for liver and kidney you have to lower it for tissue.

Is there something that I don't understand about that?

DR. FARBER: We are not going through an exercise of lowering it for muscle. We believe that the safe level for muscle based on the toxicological studies that we have seen is .1 part per million or less.

Not considering sulfa, but considering other drugs, on numerous occasions we have discovered that there is associated with a withdrawal period on that particular drug, significantly less than .1 part per million in muscle.

Now, it may be with this compound X that we see slight levels, slightly above .1 part per million in liver and kidney. Under those circumstances, we can make an upward adjustment of the tolerance.

It is a question of the total dose that man is getting per day regardless of whether he is getting it for muscle or from liver or kidney.

REPRESENTATIVE BEDELL: Apparently you believe that for liver and kidney that makes up enough of a percentage of the total dose that man gets, that if you raise the tolerance level for liver and kidney then you are obliged to lower it for muscle.

DR. FARBER: No sir, we are not saying that we are obliged to lower it for muscle. We would not lower it for . . .

REPRESENTATIVE BEDELL: If you did raise it for liver and kidney and left it .1 of one part per million for tissue, what would be the problem?

DR. FARBER: On that basis, the average individual in the population would be getting more than .1 part per million. By the proposed procedure that you are raising, exposure to man would be somewhat greater than his present exposure to sulfa.

REPRESENTATIVE BEDELL: I am sorry to take so long. What percentage of the consumption consists of liver and kidney as compared to tissue. Could you tell me?

DR. FARBER: Off hand, I can't.

REPRESENTATIVE BEDELL: Well, would it make sense if that is 2 percent, that you then, instead of having one part per million, at .98 parts per million for tissue, and raise the liver and kidney to 3 parts per million?

DR. FARBER: We are concerned not only about the average individual, but people at the 90 percentile in regard to their eating habits. It could very will be that there are certain percentages in the population that will consume kidney and liver tissue on the same day that they are also consuming pork.

REPRESENTATIVE BEDELL: This is a daily problem, apparently, rather than a long-range problem?

DR. FARBER: Yes. Our tolerances are established on what we consider to be the safe daily dose.

REPRESENTATIVE BEDELL: So the problem of sulfa is not in accumulation of it over a period--the problem is how much you consume in any one day, which might cause you serious problems because of your daily consumption?

DR. FARBER: Congressman, our major concern right now in regard to sulfa is the continuous daily administration or aborption of sulfas. I indicated that 15-20 years ago our concerns about continuous exposure to sulfas were minimal. Today the practice has changed in pork production, and we now have sulfa drugs that are being constantly administered to these animals, resulting in constant human exposure and absorption of these materials. So it is not on an intermittant basis.

REPRESENTATIVE BEDELL: I am sorry to take so much time. I know other people have a lot of questions.

I would hope I could meet with FDA to go over some of this at a later date, because I have some problems with some of the logic that we are talking about here.

I think we are all interested in safety, but I think we should use reasonableness and logic so we can try to reach safety standards, so I hope we can get together at some other time.

DR. SETTEPANI: Dr. Settepani, Bureau of Foods.

If we were to raise the tolerance in kidneys .3 parts per million, there is a definite ratio that exists between the residue levels in kidney and those that exist in the muscle, and based on numerous analyses on those two tissues, it seems that there is about one-half as much residue in muscle as there is in kidney. So, if we were to approve a tolerance of .3 parts per million in kidney, we would in effect be approving .15 parts per million in muscle and those levels are not supported by the safety data.

REPRESENTATIVE BEDELL: Nobody is asking that.

Nobody is asking that you change the level in muscle tissue. You are saying if you put in .3 parts per million in liver, you automatically have .15 in tissue. I don't think that is the request.

The request is that you leave the .1 in tissue but remove the three points in kidney.

If you are telling me that automatically if you have three parts in kidney, you have one part in tissue, I believe that the research would not substantiate that statement because I don't believe it is always the case. Surely you would agree with that?

DR. SETTEPANI: The statistical evaluation of residue data developed by USDA would tell us that it would be the case in more than 95 percent of the pigs that had .3 parts per million of residues in their kidney, so if that pig were approved we are also approving .15 in that animal's muscle.

I might add that there are also some other safety considerations no one has brought out yet, and I won't get into them unless someone presses me about it, but the .1 parts per million of residues has not been supported by an adequate safety base of data by current standards, and before we would increase any sulfa tolerance in swine, we would like to reexamine the safety base under current standards. They were approved a number of years ago under standards that are not up to our current standards for evaluating applications for animal drugs.

MR. DAMMANN: Dr. Farber, for purposes of later discussion, I would like to confirm or have you disapprove the statement that you made that at a level of .3 parts per million, and muscle tolerances not changed, only 10 percent of the violators would be affected--did you or did you not make that?

DR. FARBER: Yes. I would like to defer that question to Dr. Spaulding because I think, actually, I quoted that figure from some correspondence that he sent to us.

MR. DAMMANN: I will attempt later on in the day to discuss that. Thank you.

MR. SHARP: Roy Sharp, a rancher from California.

This is directed to the same gentleman. How does the FDA determine a 2,000-fold safety factor rather than say a 1,000-fold or 500, or say a 20,000-fold safety factor? I was under the impression that once there was a 1,000-fold, but regardless, where is a reasonable safety factor?

DR. FARBER: Well, I guess this is a question that we could go on discussing for days, but the basis of our traditional 2,000-fold safety factor which is used or applied to basic 90-day toxicity data, is derived from deliberations of the Pesticide Committee associated with the National Academy of Sciences, a good number of years ago, and this value has been applied by the agency for a number of years and we feel with a great deal of assurance in regard to human safety.

Another safety factor that is used, the 100-fold safety factor, is applied to data when it represents lifetime studies, three generation studies, and studies done primarily in the dog of at least 6 months to 1 year duration.

MR. SHARP: Might not it be possible that the 2,000-fold criteria was being used in a time when we were not able to detect such minute particles as we do today? Maybe that is something that has changed its relationship.

DR. FARBER: It could be that now with increasing sensitivities in regard to analytical test procedures, that the agency might have to consider or look at the .1 of a part per million concept, but it might very well be that the 2,000-fold safety factor will still remain in force as a traditional approach that we use for making the toxicological judgment.

MR. SHARP: Is there a possible chance of changing some of these traditional things that you speak of?

DR. FARBER: I think as science does move along in regard to its abilities to interpret toxicological data, there is always the opportunity for a change in regard to one's guidelines and standards, and I think with our agency, when we do have definite information that will result in changing of our thinking, that we will implement changes in our guidelines. At the present moment, however, I don't see it.

MR. GLOYD: Joe Gloyd. I have a question for Dr. Farber in relation to at least your most sensitive animal test that you are basing your 2,000-fold safety margin upon.

The material that I read indicates that in the 90-day test that indeed there were thyroid changes observed in the rat. However, in the 365-day test on this same group of animals the goitrogenic effect disappeared. I would like to have you comment on that.

DR. FARBER: I can't speak directly to that because I don't think I have seen the 1-year data that you are referring to.

There is another person in the audience here who has intimate day-to-day contact with this information, Dr. Gillespie.

Dr. Gillespie, are you aware of any 1-year information that has come into us?

DR. GILLESPIE: I am Dr. Gillespie, Division of Toxicology, FDA.

I am not aware of the data that Dr. Gloyd refers to. Now, I have seen some 1-year studies on a sulfonamide but it was not sulfamethazine. The most extensive data we have seen on sulfamethazine has been 90-day data.

DR. ANGELOTTI: We will interrupt the questioning at this point. We are scheduled for lunch at noon.

DR. VON HOUWELING: Secretary Foreman was talking as she walked out and was appalled by the levels in manure in our study, and I said don't forget sulfa is being fed at five times the normal use level, 500 grams. She said, I missed that point, will you be sure and bring that out in the question and answer period, our studies were at given times the normal use levels. So, it is very high levels of manure. She asked me to do that.

DR. ANGELOTTI: Okay, we are scheduled to reconvene at 1 o'clock.

This afternoon, we have a series of individuals from affected groups that want to make formal comments to us, and following that, we will have an open back and forth session between all parties. We will be back at 1.

(Whereupon, at 12:05 p.m., the meeting was recessed, to reconvene at 1:00 p.m. the same day.)

AFTERNOON SESSION
(1:10 p.m.)

DR. SPAULDING: If you will all take your seats, we will get started now.

We will be following the program as outlined this afternoon. I apologize for Dr. Angelotti not being able to be here, at least for all the session, but he told me just before he went to the lunch break that he had to check back at his office and that due to circumstances beyond his control may have to end up on the Hill this afternoon.

The first speaker this afternoon, as we get into the industries that are directly affected by our residue program and have been affected by the Sulfonamide Program, is Mr. Marvin Garner.

REMARKS BY MARVIN GARNER, EXECUTIVE VICE PRESIDENT,
NATIONAL PORK PRODUCERS COUNCIL

MR. GARNER: Thank you.

In some ways I feel the pork industry is kind of on the hill at the present time as far as the sulfa residue problem is concerned.

The National Pork Producers Council, the major organization speaking for pork producers only, appreciates this opportunity to share with FDA and USDA administrative staffs our concerns surrounding the present sulfa dilemma.

Twenty-five years ago there were six times as many pork producers supplying approximately the same amount of pork that we are today. Today's animals are yielding 60 percent less fat than 25 years ago.

These production accomplishments have been due to greater capital investment in facilities and management tools created through research and development. Sulfa use is a vital tool for our present production level.

Pork producers are today proud of their accomplishments, their product, and their identity as businessmen.

Without benefit of subsidy or protection by import quotas or tariffs, they function as truly independent businessmen in a supply and demand competitive business climate.

Since 1970, their organization has been actively developing an information and education awareness program on the benefits and proper use of

feed additives. They co-sponsored in 1970 the first Feed Additive Symposium in agriculture. They hosted the FDA Feed Additive Task Force of the pork industry in 1971. They have printed and distributed hundreds of thousands of informational fact sheets pertaining to feed additives and their proper use. FDA and USDA authorities have been regular participants in their national, State, and regional industry information meetings. Since 1971, we have challenged related industry and product suppliers to join us in a total information program pointed toward total pork producer awareness.

Therefore, we consider the statements of staff officers of Government as late as October of 1977, accusing us of being unwilling to admit that there was a problem with sulfa to be totally irresponsible. It is ironic, but it was one of the staff officers making these comments that I contacted in the spring of 1977 seeking cooperation to have government tissue testing labs conduct tests on tissue being produced in sulfa research work activated by the National Pork Producers Council.

A recent independent poll of pork producers who averaged 1,000 plus hogs marketed per year shows that 90 percent of them are aware of the sulfa problem. Twenty percent of that group have taken some action to correct some management practices that they had become aware of that might cause residue problems in hogs that they marketed. These actions ranged from ceasing to use sulfa at all, using less, increasing their own withdrawal time voluntarily, to more care in cleaning equipment and facilities. This would indicate that 70 percent of the pork producers know about the potential problem and believe their present management to be proper for supplying quality pork products to the consumer.

There are thousands of family pork production units today with $1/2 million or more invested in their pork production system. Records show that they are operating on the most borrowed capital ever in history. It is, therefore, unreal to imagine or even consider that they would knowingly and intentionally use a management practice that might endanger their cash flow for 30, 60, 90 days or longer.

We admit that there are gamblers and those who seek to defy the system. The National Pork Producers Council has repeatedly stated that we do not condone nor seek to defend those that intentionally violate approved management standards.

There are few personal hurts equal to that experienced by a pork producer when he hears, not directly but from his packer, his market man, his veterinarian, or a fellow producer, that he has been declared a convicted violator of a regulatory action by the Federal Government.

The sulfa problem is unlike most any other problem that has beset the pork industry. The economic loss, embarassment, and anguish has not blanketed the pork industry equally, but has come to rest on the shoulders of individuals and families. In most rural communities, rural

communication is still just as complete as it was in the days of the party line, hand-ringing telephone. There has been inference in Government letters and released statements that pork producers identified as producers of residue-containing hogs, have changed their marketing pattern in order to escape Federal surveillance rather than to comply with pretest clearance and compliance procedure.

We urge those who make these claims to identify the individuals rather than make shaded inferences without valid proof. USDA figures show that this is not true because percentage violations are lower in those markets not identifying the animals. We are truly sorry that a related segment of our pork industry is so inconsiderate of the dilemma now being experienced by the individual pork producer who today supplies them with livestock, that they seek to piggyback a mandatory identification program on top of such a debatable regulatory program as before us today.

It would seem more democratic that we permit the individual pork producer businessman the freedom to select that market system of his choice rather than to further regulate him into a straitjacket of Federal compliance just as hairy as that which they complain about functioning in themselves today. We acclaim, endorse, and will support the tardy, yet now filed, Boar and Sow Mandatory Identification Program. We believe that it will serve as the proper vehicle to accomplish those goals sought by identification to farm of origin.

According to USDA figures, 91.4 percent of all hog carcasses with violative residue for sulfa in 1976 were identifiable to the farm of origin. Only 12 carcasses could not be traced back. Considering this to be a nationwide program, that is an excellent record, probably unequalled in any other segment of Government. However, we are concerned why this same proven statistical sampling system fell down to 75 percent in 1977. We can answer some of this drop by saying that no attempt was made to trace back to farm of origin in some cases, even though the animals were identified.

I want to now hurriedly name some main areas of concern that we have with the present sulfa residue monitoring and evaluation program. These are being listed so that they might be considered in the redesigning of a regulatory program that will positively achieve these goals that we too want to see.

1. Scientifically-trained people both in Government and industry are expressing doubt with the accuracy of the present testing capability for sulfa residue.

2. The sampling system appears to be concentrated in certain market systems and not on a statistical random basis. In some cases, this has caused diversion of market patterns.

3. Tolerance levels are too low to be practical in view of the admitted variability within a given laboratory and between laboratories. FSQS and FDA staffs have expressed opinion that .2 ppm or even .3 ppm is a more realistic tolerance level.

4. The regions and areas of administrative design that structure the FDA and FSQS that serve this regulatory area are not conducive to efficient sample testing and issuance of prompt notice direct to involved producers so that they may make valid search of their management system, feed supplies, and other actions to identify cause of violation. The after-the-fact system now in use serves no one, from producer to consumer, and intensifies the emotional challenges now prevailing.

5. There is no uniform, effective procedure that assures the involved pork producer of being the first to be informed of his accused violative predicament. It would seem that is one right he deserves, by law, if not by courtesy, or intent to cultivate cooperation. Neither is the producer given a uniform sequence of steps to be taken to achieve lifting of his implied embargo. Neither is the involved producer given priority in the sequence of lab tests.

6. There is a glaring absence of basic knowledge of pork production and animal husbandry by some of those making on-farm inspections. Their ability to identify the actual cause of violative levels is therefore in question.

7. There is lack of uniformity of how those found to be in violation are being treated or advised or permitted to market animals. It appears that size of production, vocal ability, and political contact achieve limited marketing capability not uniformly made known to all in violative position.

8. There has been too much intergovernment and interindustry expression of who is at fault and too little visible effort toward solving the problem until today. With 90 percent or more of our pork producers aware of the problem in proper use of sulfa, and with few exceptions striving to comply, it is amazing that the reported violation level climbs. We do not believe that trend is realistic.

Therefore, we recommend that an Evaluation Team of FDA and USDA regulatory research scientists and industry be formed to immediately investigate all facets of the present sulfa residue problem. We further recommend that this team be directed to develop and present for enactment a program to be mutually approved by FDA and USDA that would achieve the goals intended and to correct those weaknesses now apparent.

We believe producers, industry, government, and consumers deserve this effort. In addition, members of Congress have expressed interest in this approach.

During this interim period, we ask that since there is research-proven correlation between the compatibility of tissue and organ in man and pig, that the vast toxicity data now available on sulfa and man be used to qualify raising the present tolerance level from .1 ppm to .3 ppm in the liver tissue of hogs marketed, before being declared violative. Data shows that this allows muscle tissue to be free of residue, in most cases, at any level of concern when you consider the percentage and the ounces and minimum ounces of this product eaten per person per years.

We would certainly be supportive of this kind of program, and in order to clarify some of the statements we made here, I would like to call on a couple of producers that had the actual experience with this and let them relate to you exactly what happened to them as pork producers in this type of situation.

Dick Brand, would you come up please, and make a few comments.

This is Richard Brand from Hopkins, Missouri, a pork producer.

REMARKS OF RICHARD BRAND, PORK PRODUCER,
HOPKINS, MISSOURI

MR. BRAND: Thank you, Mr. Garner.

Mr. Chairman, ladies, and gentlemen.

I am an active pork producer located in a high livestock production area of northwest Missouri. My visibility as a pork producer has multiplied many times since March 1977. At that time, my daughter became the National Pork Queen; and as such has traveled about this Nation appearing in behalf of the pork industry and in cooperation with the National Pork Producers Council programs. My wife has accompanied our daughter to these many pork industry functions during the year, and as a result, our family has an increased awareness of our problems confronting the pork industry.

We therefore redoubled our efforts so that we avoid any problems that might tarnish our daughter's efforts or our pride in the pork industry.

November 1, 1977. After checking several potential market points in our area, we marketed 168 hogs through a marketing point at Bedford, Iowa. This was the only market, of those contacted, that identified the hogs to farm of origin, due to the system of marketing we selected that day. These hogs were later slaughtered at a packing plant in St. Joseph, Missouri.

November 18, 1977. We received a phone call from Dr. Nelson, MPI office in Dallas, Texas, informing us that they had checked one of our hogs from those marketed and found a sulfa residue; but it was not bad enough

so they sent the animals on through. However, he informed us that we could not sell any more hogs until we had pretested five head of animals and that they were found to be free of sulfa residue. He said that a certified letter would follow to confirm this call.

November 19, 1977. We received a certified letter from Nelson, but it did not contain any procedure or directions as to how, when or where we were to deliver animals for the pretest.

At this point, we contacted Mr. Garner for advice on how to proceed. He advised us to first get samples of the feed we had in our feeders, even though it might not be from the same batch that the supposed violative animals had access to.

He advised us to then contact the MPI person in charge at the same plant that slaughtered our original animals and to follow their instructions on delivery of animals and other procedure.

December 1, 1977. A representative of the FDA called to inform us that he would be visiting our farm the next morning to help us in finding out why our animals were in violation.

December 2, 1977. The FDA man arrived at 8:40 a.m. and was requested by our boys to come out to the field where I was working. He in turn refused and instructed the boys to tell me to meet him at the house. He looked over our hog setup and took some feed samples. It was quickly evident that he was not experienced in hog production or management by the terms he used and the questions he asked. It was very apparent that his retired military position had not prepared him well for his service with the FDA in making visits to farm pork production units. Despite seeing our feed handling system, he asked for feed tags. We explained that we got our concentrate in bulk form and that it was mixed with our farm-grown grain, but I offered to go into town and get a feed analysis chart of what we received in that bulk delivered feed.

The FDA man accompanied me to the feed dealers where he obtained the analysis information. The dealer asked if he was questioning our feeding operation and he said "Yes." Then the dealer asked why the FDA was harassing the pork producer, instead of working with the feed company.

The FDA man replied that he was not harassing the producer, that the farmer was responsible for what he was using and said "This terminates our conversation." He then turned to me and said, "But I'll continue with you."

Our point is that if the FDA sends out a person to supposedly help the pork producer, he should at least be familiar with livestock and management and not be quite so belligerent.

December 8, 1977. We called the USDA inspector at the packing plant in St. Joseph, Missouri, to find out the procedure for sending in pretest hogs. The inspector said he didn't know and suggested I call someone else in the packing plant. Not knowing who else to call, we called back to Dr. Nelson in Dallas, Texas. He in turn said he would make the call to the packing plant to arrange for the pretesting. We called our original marketing point, and they offered to take the animals down for us but we elected to deliver our five animals separately ourselves. The Bedford, Iowa, marketing point made the arrangements at the plant in St. Joseph and then confirmed them with us, giving us the name of the person that would receive the hogs at the dock.

Our son and another young man working for us took the five hogs the 60 miles to the packing plant. They were unloaded at 11:50 a.m. and taken directly to slaughter after our son stressed the importance that these hogs be identified to us and placed in a clean pen until slaughter.

December 9, 1977. The morning after delivering the five hogs to St. Joseph, we received a call from our local buying plant informing us that the hogs had been identified, had been slaughtered; but inadvertently, the livers had been lost and they would need five more hogs for pretesting. The temperature being below zero we were still trying to harvest corn that was 60 days or more late due to wet weather and now this inept handling of a very serious matter to us was a bit too much.

My wife called Dallas and explained our situation and that we had done everything to comply, but others in the system had failed their responsibilities. He said this was an unusual situation, but that he would call St. Joseph and they would take muscle samples only, but that they would get liver samples at another time without retention. This was about 24 hours after the test animals had been slaughtered.

December 15, 1977. Dr. Nelson called from Dallas and informed us that the muscle samples were clear of any sulfa residue and the packing plant had been so informed and that this cleared us to sell hogs, but that they would like to take a liver sample at some future time without retention of carcasses.

December 17, 1977. We received letter from FDA saying that no sulfamethazine was found in the feed samples that he had taken at our farm.

December 22, 1977. We called the packing company buying station to inquire why we had received nothing for the hogs, even though they were finally cleared as a healthy meat supply.

December 27, 1977. We received a call from the packing company in St. Joseph saying that they had just been informed by USDA that the hog carcasses could be released. We informed them that we had been told this 2 weeks earlier and understood they had been informed at the same time.

December 29, 1977. We received a check in the mail for the five hogs. It was $268.81, approximately half of the actual value of the animals when delivered to the plant.

In summary, we are proud to be pork producers and proud of the product we produce. We are pleased to have our daughter speak in its behalf. We conduct our pork production business in an honest manner. We have made every effort to follow known management procedures to comply with all regulations.

We believe that we and all like us in the pork industry deserve a more competent, a more accurate, and a more fair and business-like procedure by Government regulatory people. We resent immediate conviction, based on a one-animal test, using methods that are in question by scientists and being forced to bounce about in the uncoordinated entanglement of Federal bureaucracy not structured to serve or protect anyone, from producer through consumer.

Thank you.

REMARKS OF SAM KENNEDY, PORK PRODUCER,
CLEAR LAKE, IOWA

MR. KENNEDY: I am a pork producer from Clear Lake, Iowa.

As time is short I would only relate our experiences.

I will preface my remarks with a brief description and history of North Central Iowa Pork Producers, Inc. (N.C.I.P.P.). NCIPP is an Iowa corporation organized in 1974 by a group of farmers for the purpose of marketing quality breeding gilts and market swine of a very high health status. The facilities were built with this goal in mind. Therefore, the facility is totally confined even without windows in the swine housing area. Even though separate buildings are used, they are connected by inside alleyways. All personnel shower before entering.

A flushing system is used for the daily removal of waste. However, this is accomplished beneath slats so that animals have no direct exposure to the recycled water. The unit is surrounded by an 8-foot cyclone fence that remains locked at all times.

An isolation building was built into the fence line for the purpose of screening animals during population and for safe withdrawal from the facility. Animals are moved by tractor and trailer from the facilities to the isolation buildings and moved from there to commercial farms or slaughter by means of our own vehicles. Once an animal reaches this building, it never again returns to the facility.

The unit was populated with accredited SPF (Specific Pathogen Free) stock. From a health and disease evaluation, this type of animal enjoys the highest status available for commercial production. As we work with many segments of the swine industry, we are represented at almost all industry meetings. I would suggest that we were as aware of the "sulfa situation" as any producer. However, always with the thought that as we do not use the drug, we would not be affected.

Approximately 100 tons of feed is consumed in the facility per week. Feed is mixed and delivered on a custom basis from a local co-op elavator. We have supplied the ration formulation to be used and do provide a vitamin and trace mineral premix to the elevator for our use. All feed is pelleted and delivered to a 50-ton bulk bin outside our perimeter fence where it is then blown underground to the different storage bins located near the housing buildings. A separate feed bin is located for the isolation building. This system was designed that if at any time antibiotics or drugs requiring a withdrawal period were used in the facility, an unmedicated feed could be used in the isolation building for the proper withdrawal time.

However, it should be noted that at no time since this facility was built was sulfamethazine or any form of sulfa been incorporated in the growing finishing rations nor has any form of sulfa been used as a feed additive for the nursery farrowing or gestation rations. Also, there is not a means by which a water soluble sulfa can be used in the grower or finisher units.

On August 8, 1977, about 3:30 in the afternoon, I received a telephone call from a USDA official advising that on a load of hogs slaughtered on July 20, 1977, the USDA had found sulfa residues above the tolerance level. This gentleman was both considerate and helpful. He advised that we would be receiving a quarantine in the near future. I was not at that time or am I now sure if the quarantine started from the time of the phone call or from the time we received the official notification with instructions on how to remove the quarantine on August 20, 1977.

I assured this official that we had never used sulfa in our program, nor had it ever been used in our facility. He stated "the test was 90 percent accurate." To my thinking, that easily explained the situation. We were one of the fortunate 10 percent.

My first thought after receiving notification was that a mistake in identity had been made. Only one sample was taken. That same afternoon, I phoned our packer and made arrangements for a select group of five to be brought down early the following morning. One of our employees left shortly after 5:00 a.m. the next morning, delivered the animals to the slaughter plant, followed them through the packing line observing the plant veterinarian as he took the samples.

He then met me at the local airport where I flew the samples to a private laboratory. I reached the laboratory about 3:00 p.m. on Thursday. Late Friday afternoon, I had the results. They showed the liver and kidney tissue with sulfa levels above the tolerance level.

My next thought was that if proper identification had been made, then our feed company must have supplied us with feed containing sulfa. I immediately took the following steps.

1. I advised our cooperative feed company of the situation.

2. We emptied the feeders and supply bin in the isolation building by hand, cleaned out all feed dust and refilled with new feed from the cooperative where they had taken every precaution to make sure that uncontaminated feed was delivered. This was accomplished by cleaning and flushing the mill, and also making sure the feed truck delivering the feed had not delivered a feed containing sulfa.

3. We notified the chemical company manufacturing our vitamins and trace mineral premix to send in a sample for analysis.

4. We retain samples of every ration delivered for approximately 1 year. We sent in the last 40 samples dating back to June 10 to another private laboratory for sampling.

On August 17 after the pigs in the isolation building had been on new feed, we sent another five pigs to slaughter and followed the same procedures. Once again, the samples were positive. By this time our slaughter pigs were backing up. I asked the USDA official (with whom I was in almost daily contact) what we could do. In checking he advised that since in both samples our muscle tissue was not above the tolerance level, our hogs could be marketed if the liver and kidneys were condemned.

With this information, I talked to the several slaughter plants where we were marketing hogs. One plant would not bother with the procedure, one plant thought it would be quite expensive and the plant where we had been submitting our samples agreed to follow the procedure for what I thought was quite a reasonable price, 50 cents a head. However, because of this situation, we did not have the competitive markets available that we normally use in marketing. Therefore, our base price was approximately $2 lower from what we would have obtained if we had not been restricted to the one plant.

We then received results of our feed samples. These first results showed levels of from 50 to 150 grams of sulfa in each and every ton. This was not possible. The test used we later found to be nonspecific. These feed samples were transferred to another private laboratory and then to another. In the meantime, we sent yet another sample of our feed to a different private laboratory.

On August 22 we were called upon by the local representative of the FDA who informed me that we did have a problem and was interested in discovering the source of that problem. I brought him up to date on what we had learned and advised that his first stop be with our feed supplier.

At this time, I did not doubt the USDA's word that we did have sulfa residues. The following day I was out of town and arrived home late that evening. Our manager informed me that a representative of the FDA had stopped at the facility, explained his desire to tour the facility and take some feed samples. As no one is allowed to enter our facility without complete Board of Director approval, our manager had denied the FDA respresentative access. Apparently, he became quite excited and called his main office. They were going to send several individuals to visit our operation.

The next day an FDA representative informed me of his desire to visit our facility. I asked him if he had been on any other swine operations earlier that day and he mentioned several. (The few times that we have granted approval for an individual to enter our facility, we have required at least two weeks whereby the individual has not had contact with swine, feed mills, etc. This is required even of our local veterinarian.

I also asked him if he had inspected the cooperative elevator. He said, "Yes," and had taken several feed samples and samples of dust around the mill. I asked him if he had the results yet and he said, "No." In fact I never did hear those results.

I suggested that we would let him enter the perimeter fence and take samples out of any of the feed storage bins of his choosing around the facility of his choosing. Also that as the isolation building is open-fronted, he could watch while one of our employees took feed samples at this direction from the feeders or feed troughs and handed them directly to him. He refused by saying that he was supposed to take feed samples from the feeders used by the hogs personally. Nothing less would do.

I also mentioned that he could inspect our office and laboratory and make an inventory of all drugs used in case this might be the problem. This he did. However, I still denied him access to the facility. There was nothing for us to gain by having him inside--only increasing our risks of bringing in an unwanted disease.

I discussed the authority of this FDA individual with our attorney as to whether he did have the legal right to search our production unit. His interpretation was that if we were a feed warehouse or a feed manufacturer this would come under his jurisdiction; however, perhaps his authority under the given circumstances was questionable. We never did take this matter further as he did not again make any attempts to gain entrance.

I do not wish to be misunderstood in this case as we were searching for help. We did have a problem. We did not know how it could be solved. However, this individual knew very little about the sulfa residue problem. Less than I and I knew very little.

On the other hand, if we had granted this individual access to the facility after he had been on other swine operations during the day and then had broke with a chronic disease such as pseudorabies or T.G.E. who would have been responsible? Would the FDA have compensated for the responsibility? Or would this have just been an added expense for us, the producer?

By this time, I was spending 4 or 5 hours a day on the telephone with USDA and FDA officials in Washington and in Kansas City, with diagnosticians from private laboratories, with veterinarians and State officials, professors from our own State university and chemists.

Fortunately, I did have courses in chemistry and organic chemistry in college. Also I was not so far removed that I had as yet forgotten all of it. Without this background it would have been impossible for me to begin to understand the testing procedures used. After several days of this, I began to realize that there was another variable. Perhaps the biggest variable was USDA's testing procedures.

I did not find a single person associated with the universities or in private industry that did not feel that there was more error in the test at the level of .1 part per million than accuracy. I also found there were many individuals in the FDA and USDA that did regard the tests as "fairly accurate--the best we have."

We did receive the analyses on our vitamin and trace mineral premix, and they were negative. Our cooperative elevator did have an identical experience with their feed samples, the first using a nonspecific test showed them positive. Later a more specific test was run and the samples were negative. All of our feed samples came back negative the second time.

On August 31 we again submitted an additional five pigs for evaluation. Nothing had changed. They were on exactly the same feed rations they had been fed all along. Samples were sent by U.P.S. to the private testing laboratory.

While taking these samples, the plant veterinarian assured us that even if they were negative, our farm was on the blacklist and from this time our samples would be drawn every time we went to slaughter. The results came back negative or below tolerance levels. We again could market our swine competitively.

On October 20 I received test results from one of our private testing laboratories that showed two of our feed samples including the feed from the isolation building showed .7 parts per million sulfa. They were using a test that had not been used on our samples to date. However, although at that time there was not adequate data available, it looked like this level would be too low to cause .15 part per million residue in the tissue.

Out of pocket costs had now reached over $20,000 in a short but long 8-week period. We decided to end our ordeal until such a time as we again had the problem. Since then we have marketed several thousand head of swine. I assume some samples have been taken; however, I have not seen the results. It is now my understanding that these results are available to the producer upon request.

However, again I am not sure who is responsible. Who should reimburse us for the money and time spent? Is the feed company at fault or is the USDA? Certainly by any stretch of the imagination the producer in our case cannot be responsible. Somewhere a mistake was made.

DR. ANGELOTTI: I regret I am going to have to leave. Mrs. Foreman and I have to go up the Hill to speak to some committee members today.

Dr. Fullerton, I would ask you to come up and please preside over the rest of the meeting: If it is at all possible, I will return as quickly as I can. If I don't get back, Fred, would you please carry on. I am particularly interested in what is coming up in the way of discussion in response to these things that are being said to us now. I will want to know personally from these folks the details of what had transpired. So, let me offer you my apologies, I am sorry, but I do have to leave.

REMARKS OF MYRON DAMMANN, PORK PRODUCER, STATE OF MINNESOTA

MR. DAMMANN: Ladies and gentlemen. I am a pork producer from the State of Minnesota. Over the past 6 months I have been corresponding with the USDA and the FDA regarding the sulfonamide issue. Most of you have received or are aware of the ongoing correspondence and the many areas of concern discussed. They also contain the case history of my having sold one alleged violative pig containing 0.2 ppm and the evidence demonstrating how this could not have happened from feed manufacturing errors or farm management errors.

Therefore I shall limit my discussion today to the following general area: Current sulfonamide testing procedures and their corresponding inability to protect producers against being falsely accused.

Concerning the analytical tests used to determine violations, I question the quantitative analysis using the 1968 Tischler adaption of the 1939 Bratton-Marshall Test. As I studied these papers, I found that the

Bratton-Marshall reaction measured the diazonium salt of the sulfonamide molecule. Many other primary aromatic amines can and are also included in this measurement. Likewise other compounds in feedstuffs and tissue would show in these quantitative readings. Perhaps the best example would be that of the vitamin P-aminobenzoic acid because of the chemical similarity between PABA and sulfonamides.

In no instance have I been able to find a statistical reliability study conducted of this quantitative method or have been supplied that study by the Government. I have been told by the USDA MPI that they have recognized the occurrence of interfering substances in the sample which have an effect on the analytical method; but, that method would be used until the FDA determines that there is another method that they will accept as valid.

The FDA and the USDA have attempted to justify the use of the Tischler method by using TLC (Thin Layer Chromatography) and GLC (Gas Liquid Chromatography) which are used to identify the presence of a specific sulfa drug even though that level may be well below regulatory level. In some instances mass spectrometry is also used but it is not a part of the official instructions to the laboratories.

The FDA and the USDA say these chromatography procedures confirm the findings of the Tischler method of the Bratton-Marshall Test. This is not the case at all. TLC and GLC are screening and identification procedures. There is no confirmation of the quantitative findings of the Tischler volume readings. The Tischler procedure is not even performed unless there is a speck of a sulfonamide identified under TLC and GLC.

If a sample had some sulfa drug identified in TLC and GLC, all of the quantitative reading of the Tischler method which is used to establish a violation would be considered due to sulfa. Another sample which could have the same identical Tischler reading--yet negative under the TLC and GLC--would be considered not violative.

WARF Institute at Madison, Wisconsin, agrees with the above. I have found no one in the private sector who will say you can test accurately to the levels you are testing using the present analytical procedures. In fact, WARF had tried to show the USDA and the FDA more exacting procedures. Even Dr. Bevill's Blood Plasma Test has a reported 5 percent-10 percent inherent error.

If one would go through the procedures of the analysis, you can understand how human error could occur beside inherent errors of the tests themselves.

I have been asked by my State MPI director if I knew of an analytical procedure, a laboratory or a staff that was always 100 percent accurate. That is true, but what protection does the existing monitoring program provide to protect the producer against that happening?

According to the Washington Report, in the January 1978 issue of Hog Farm Management, Dr. John Spaulding stated that very few sulfa violations are found in the 0.1 ppm to 0.2 ppm range because of the USDA practice of screening out background readings. Dr. Spaulding said a modest easing up on the violative level would not help most producers much. I quote from a letter addressed to me August 10, 1977, also from the USDA MPI as follows: "Although we realize it is of small comfort to Mr. Dammann, we do want to report that only a small percentage of violators have test results as low as 0.2 ppm."

I requested from Dr. Angelotti on December 27, 1977, the number of alleged violations at each tenth of ppm level from June 1, 1977, to December 1, 1977. The following information was supplied:

PPM	No. of Violations	Percent of Total Violations
0.1-0.2	331	31.7
0.21-0.3	177	16.7
0.31-0.4	106	10.1
0.41-0.5	66	6.3
0.51-0.6	49	4.6
0.61-0.7	42	4.0
0.61-0.8	19	1.8
0.81-0.9	15	1.4
0.91-1.0	19	1.8
Over 1.0	222	21.2

From this information we find that 3.7 percent of all alleged violations fall into the 0.1 ppm-0.2 ppm range. This range contains the largest number and percent of alleged violators--the very range Dr. Spaulding and his staff state is too small to be concerned about. Frankly, the inherent test errors, human errors in performance of analytical procedure and other potential sources of error are not screened out. The 0.1-0.2 ppm group contains more alleged violators than the total violations above 0.6 ppm. I personally consider levels at 0.6 ppm and above are due to producers who may not be following proper techniques.

It is extremely interesting that at 0.3 ppm and under we find 48.4 percent of the alleged violators. This is the group of producers who have done everthing humanly possible to avoid violations having followed the advice

of the NPPC, the USDA and the FDA. The NPPC has asked that the level be raised to 0.3 ppm to screen these out. In the first place the tolerance level of 0.1 ppm was not selected based on scientific fact alone and allows a human safety factor of 2000 times. You cannot accurately screen out background inference since it is impossible to analyze an alleged violative liver in a nonviolative state.

In the actual sampling phase a producer has little protection against mixups in tatoo identification at laboratories or poor sampling techniques at the slaughter point. Since I was aware of the possible cross-contamination between lots of pigs through urine at the slaughter point, I delivered my five-head retest group directly to the kill floor. I observed sampling techniques by the top USDA officer at that plant that cannot be condoned.

The same knife with blood and body fluids from other animals was used to remove all tissue. Three livers ended up in the same tray with blood and body fluids running from one to another, making it difficult to determine which liver came from which hog. Has not anyone instructed these people in proper sampling techniques? You are trying to measure tenths of parts per million.

Since condition of sample is important to accurate analysis, I asked the USDA what percent of the laboratory forms had the condition of sample noted in the space provided. I was informed by the USDA MPI that 98 percent of the forms have this noted. Since I have forms on eight pigs sampled over a 3-month period in which the condition of the tissue was never noted, I challenged that figure.

I was then told by phone on January 11 to strike that estimate since they had no basis for making it at that time. One important statistic is as the number of random samples in November were reduced to approximately one-half of the peak periods months, the violative percent was reduced dramatically to only 8.4 percent.

Research now has been concluded at the University of Illinois that demonstrates that a pig can pick up residue violations just by coming in contact with the urine and feces of a pig fed sulfonamides and/or under a therapeutic level of sulfonamides. This is due to the browsing habits all animals and especially true when placed in a strange environment as encountered in the marketing processes.

Who is responsible for washing hog buying stations, trucks and holding pens at packing plants while a steady stream of hogs keep coming in? If the management of the feed industry is as bad as the USDA suggests to me it is, how can I be responsible for the feed supplied in the marketing process?

According to an Elanco scientist, 1 ppm of sulfa consumed on the day of slaughter will result in 0.1 ppm in the tissue. Just a milliliter or so of sulfa consumed the day of slaughter will cause a violation. We know about 28 percent of sulfa ingested is excreted unchanged in the urine. This simply means this program cannot operate at a slaughter point level.

There is no justice or validity in imposing economic sanctions on a producer based one-pig sample. Different pigs have different physiological capabilities. According to MPI, multiple factors can alter normal excretion rates. Would you accept as valid proof the response of one individual animal to a particular substance? If that were true research would be very simple. You can attach only an extremely low degree of significance to a one-head sample. I suppose that is why you call for a five-head sample for retest. Yet, explain to me how you could have a five-head sample from a lot raised in the same environment, four of which would be negative to sulfas and have one which would be positive at 0.12 ppm and therefore be in violation.

Today you still have a timelag of 35 days to as high as 81 days from the date of slaughter of the initial alleged violative pigs and notification of the producer. At that late date the producer has usually no more pigs left in the lot, and the feed in question in most instances is gone. He has no evidence in most instances to defend himself against a bum rap.

The FDA estimates they investigate 50 percent of these cases approximately 48 days after the initial violation with a maximum date of 114 days. Now how can you conduct a sane investigation 48 days or later after the fact? I am particularly concerned about that since learning that feed manufacturers are legally required to hold retained feed samples only 60 days after manufacture.

No producer is provided a report of these investigations. I had to request the FDA investigation of my farm, feed supplier and veterinarians. Then under the Freedom of Information Act I had to request the findings of these investigations and had to follow the same procedure to get the analysis of the seven retest pigs, which were all negative. Now, if a producer does not get a copy of that investigation, how can the contents of such investigation be verified? In no way is a producer given any assistance by the USDA.

I am not against residue monitoring if it is done in a constructive and just way. Monitoring programs must be constructed with safeguards to make sure one is indeed a violator before you call him one and inflict economic burdens on him. The present sulfa monitoring program does not serve either the consumer or the producer. Future monitoring activities must be studied both inside and outside the Government with input from both sources based on a rational, scientific basis.

The present monitoring program literally calls for zero usage by the industry due to the shortcomings I have indicated. It is the producer pitted against a stacked deck and loaded dice.

I was told the following in a letter received December 15, 1977, from the MPI as to what was required of me to protect myself from my Government, and I quote:

"In my view, one must first ask what evidence there is that the herd was in fact in compliance prior to our testing. A producer should be satisfied that his management system includes: (1) quality assurance test for feed constituents that disclose the presence and absence of drugs in specific feeds; (2) definite checks on the performance of employees in carrying out instructions; (3) systematic sampling of animals for residues of drugs used. Records of the operation should show adequate controls and consistent compliance with respect to residues for the past year. If these conditions are met, then the herd can be said to be in compliance prior to our sampling."

Such an insane program that I would be expected to undertake would cost me, a small producer, approximately $30,000 per year just to feed test alone.

I and no one else wants to defend a real violator. But what I fear the most is an ill-conceived and ill-administered monitoring program. I have suffered enormous losses from one of them. I am a purebred breeder.

Those who propose these counterproductive decrees not based on scientific fact for the agricultural community will also have to accept the responsibility for eventually higher food cost. All the boycotts in the world will not bring down food cost if the product just is not there.

DR. FULLERTON: Ladies and gentlemen, we are running about a little over an hour beyond time and have some more speakers here. I would like to ask you at this time, anybody who has a particular time press to come on first, or can we get on to the next speaker?

REMARKS OF RALPH LOGAN, CORPORATE MANAGER, HOG PROCUREMENT AND AGRICULTURAL EXTENSION SERVICES (REPRESENTING NATIONAL INDEPENDENT MEAT PACKERS ASSOCIATION AND AMERICAN MEAT INSTITUTE)

MR. LOGAN: Dr. Fullerton, I would like to express as a member of the American Meat Institute and National Independent Meat Packers our very real thanks for the privilege of being here today--both to listen and to take part in this dialogue.

I would hope, Dr. Fullerton, you would convey our thanks to the Assistant Secretary and to the Administrator, Dr. Angelotti. We do take pride in being asked to be involved because we have been asking for this kind of

meeting for several years. I think the dialogue that has taken place so far has been most helpful.

In the notice of today's hearing, Dr. Angelotti calls our attention to the purpose of the meeting, i.e., to provide an opportunity for a frank exchange of the issues surrounding this problem and to open avenues which may lead to its solution. Today, we have heard several experts in the field testify to the problems surrounding this issue.

You have heard this most recently from producers who have had the problem of trying to find out just exactly what their problem was and how to extricate themselves from that problem. Now you are hearing from a member of the part of industry that also finds themselves with a problem, a very serious and deepening problem.

As an industry, we feel strongly that the first step out of this complicated maze is the mandatory identification of farm of origin for all swine submitted for slaughter.

We certainly are sympathetic to the confusion and the complexities that deal with the ultimate solution of the problem, but at the same time we must be realistic in indicating that there can be no solution without a complete identification and trace-back ability of the animals involved. As industry members, many of us have been identifying animals by individual owner for over 20 years.

I would like to acknowledge the fact that with me today is Clayton Kingston of George Hormel, Vice President for Pork Operations, and probably one man in the industry who knows more about identification than any other that I am aware of.

We began this program for the three reasons indicated later, and have continued to expand upon it during these 20 years. Now, however, we are finding ourselves in the uncomfortable position of having to deal with discrimination as a result of this program and in view of the fact that much of the attention for sampling of residue is directed toward these particular animals. This is discriminatory or partial identification.

A recent survey taken in March of last year, by members of the American Meat Institute's Pork Committee, indicated that in excess of 60 percent of the animals slaughtered by members of the AMI were traceable back to the farm of origin. Thus, we do have precedent in this country for being able to identify animals to the owner in a rather simple manner. A tattoo iron instrument of about $50 will get the job done. As a result of being able to identify swine, three distinct and cumulative areas of progress have resulted:

1. All or most of our meat quality improvement has come as a result of identifying breeding stock and the resulting progeny.

2. Market systems such as carcass grade yield that reward this improvement on a carcass basis or live merit system have developed--totally dependent upon identification of the lot or source from which the animals were bought.

3. The ability to analyze different sources of supply and determine which are the most acceptable from the processor's standpoint have developed.

Under the banner of consumer protection, "random" sampling for subtherapeutic drug residues is increasing with significant ramifications. Today, producers all over this country are confused, concerned, and in most instances infuriated over the sampling program for drug residues--that its final effect is contravening the free flow of the market system in an unbelievable, discriminatory manner.

For the most part, producers are marketing hogs in good faith; processors are buying them in good faith, and yet a bias is set up as a result of the inequities inherent in a partial identification program. And thus, we have introduced an enigma--partial identification. Here we have one of the greatest inconsistencies imaginable; it is comparable to flying or attempting to fly with one wing. It just simply will not work.

Much publicity has been given to the many producers who have had herds, in effect, quarantined because their hogs were randomly sampled and found to have an excessive residue problem. I would submit to you, that in actual practices, the samples have not been random, and in fact, have been narrowed down to or zeroed in on as sources that, in effect, could be identified specifically. If this premise is correct, what then is the fallout? My impression is that the producer's and processor's tolerance level is decreasing, and we are dangerously close to the explosion point.

Under partial or discriminatory identification, I can see the consumer losing meat quality, the producer losing a market, and the processor losing control of his procurement activity.

If you view these as only a figment of the imagination, consider this. One major packer in the Midwest, this past fall as a result of discriminatory sampling stopped identifying all hogs for a period of time. By doing so, he denied producers in his area a market to sell their hogs in a normal manner because he could no longer justify exposing his clientele to the risk of having their hogs tied up for weeks waiting for a sample to be cleared. Others have considered similar or even more drastic action, and we believe that if total identification does not come the industry will move to no identification. This would be a giant step backward for the swine industry.

The simple irony of all of this is that as producers refuse to sell where only hogs that are identified are sampled, they will sell where they are not identified. These same hogs are purchased by some packer, conceivably the same packer from whom they fled--and if there was a real problem, it would be impossible to track down the offender.

Furthermore, the inefficiencies of moving livestock around the country to circumvent the sample testing can only lead to increased costs which ultimately are going to be passed on to the consumer. This approach makes one wonder just where the consumer protection is under such a program, and we recently have been assured that the sampling program is not going to decrease, and in fact, will broaden. Make no mistake--no packer wants to present product with residues or adulterants; but the existing program does not protect. It, in fact, lends itself to do just the opposite.

Additionally, many of the "offenders" caught under this inconsistent system are among the outstanding hog producers in the United States who have worked for years to improve the animals they ship to market.

It would seem to me then that we can conclude that under the present partial identification program we are accomplishing:

1. Reduction of market opportunities and efficiencies.

2. Creating serious economic impact on a discriminatory basis both to the producer and processor.

3. From the standpoint of the protection of the consumer, we are not in any sense protecting this group. In fact, we are very probably masking a problem, if one does exist.

Sulfa follows TB, arsenicals, brucellosis, heavy chemicals, and metals. As an industry, we are concerned about the possibility of the loss of an entire day's production. If, by some coincidence or quirk, a foreign material were introduced into the carcass of one of these hogs and then picked up in sample, what corrective action could the inspector take? Would we have to condemn as inedible the entire day's production--or would we trust to luck that this was the only individual involved. It seems to be much more logical that total identification of all of the sources would be even further protective of the consumer.

A continuation of the status quo will not solve the problem that the USDA and FDA indicate is real. Equally important, the continued use of sub-therapeutic drugs is apparent unless those drugs are banned from the market. This, to us, would seem to be irrational and counterproductive. Recent testimony before the Office of Technology Assessment Board would indicate that the broad livestock industry has need of many of the drugs for use in efficient livestock production--not to inhibit diseases but to increase growth and feed efficiency.

Therefore, the conclusion must be drawn that if we do indeed have violations, we must be able to identify 100 percent of the animals submitted for slaughter, and eliminate the opportunities to circumvent in those plants or markets that today are identifying. No longer can we tolerate as an industry, the movement of "hot dogs" to markets that advertise the sanctuary of nonidentification.

I have, on the table, a release from the FSQS concerning the monitoring program for swine sulfa residue through November 30, 1977, that shows that 7,122 samples have been drawn, year-to-date, and of these, 1,937 were taken from markets that had no possible way of identifying owners, and that the percent of violations was equally as high as those where the producer could be identified. Recently, we have seen indications that there are more violations occurring in the market samples than in the producer samples. This, of course, is a point that we just referred to in allowing santuaries to exist.

Many producer groups are indicating their concern that we do not have total mandatory identification, and in fact, I have here a letter from the National Farmers Organization addressed to Mr. Jack Waldock, the Pork Committee Chairman of the American Meat Institute, indicating complete and total support for this program.

We do recognize, as an industry, that there are serious problems and complexities in the area of eliminating drug residue. We do recognize that there are problems with the sampling techniques and the integrity of the sample itself. We do recognize that there may be cross-contamination between hogs that have received sulfa and hogs that have not received sulfa. Most of all, we do recognize that there can be serious ramifications from a program that could create quarantine of herds or any other counterproductive measure at the farm level.

The economic ramifications of a program that could literally destroy many of our producers as a result of an inconclusive or erroneous test is too horrendous to contemplate. Therefore, we believe this program should be in two phases:

1. An immediate call for identification of all hogs back to the farm of origin upon presentation for slaughter.

2. The beginning of a full scale testing program under the strictest kind of control that would assure integrity of the sampling procedure and quick turnaround times along with recommended withdrawal periods, and enforceable penalties for those manufacturers of feed that do not present any buyer all the necessary information about that specific feed.

Buyers must be protected from poorly designed feed mills and elevators that do not have the ability to segregate feeds with medication.

We further would advocate the testing and research to be done by educational institutions as well as the Department of Agriculture staffs and that this testing take place over a period of at least 6 to 12 months. We feel that only with these two programs in tandem can we accomplish the assignment that we feel is the responsibility of the total agricultural system from the producer all the way through to the U.S. Department of Agriculture.

In the past, we have been very concerned with our credibility as an industry; we have jealously avoided any controversy that could create the impression that what we produce is bad. I would impress upon you that a positive step at this point might be to take the bull by the horns and face the situation realistically and demand as soon as possible mandatory identification for all hogs submitted for slaughter. In this way only, we believe this area of concern can be confronted and eliminated.

We in free enterprise hate to ask for more regulation, I assure you--but we believe this a far better solution than the alternative of stopping our current tattooing programs.

Thank you.

DR. FULLERTON: Next on the agenda representing the Animal Health Institute is Dr. Carl Pruitt, Chairman of the Tissue Residue Assay Task Force.

REMARKS OF DR. CARL PRUITT, CHAIRMAN, TISSUE RESIDUE ASSAY TASK FORCE, ANIMAL HEALTH INSTITUTE

DR. PRUITT: Dr. Fullerton, Dr. Spaulding, thank you very much for having us here.

The Animal Health Institute is composed of drug manufacturers, and the member companies probably produce and distribute most of the medicaments used in animal feeds. I think that as a point of fact we have been concerned with drug residues and tissues of animals being used for food longer than anyone in the room. My task force that is concerned with methodology for determining the amount of drug residues in food has been in contact with both USDA and our colleagues in the Bureau of Veterinary Medicine. We are certainly concerned about the dilemma that has been outlined today.

We would like to offer our services, our concerns, our resources to help solve this unfortunate dilemma.

We believe, very firmly, that the products that we manufacture and distribute are safe and effective when they are used according to the directions on the labeling.

You have heard today many other ways that meat can be contaminated with drugs, even though the producer follows the labeling precisely. We feel that--and again it has been demonstrated here today--85 or 90 percent of all the pork producers inadvertently or otherwise are following the directions; they are producing wholesome meat for the American consumer, at a very reasonable price.

We think that is a good record.

Despite that record, we are concerned about the 10 or 15 percent who for one reason or another are having problems.

We stand ready to do more than our share to solve those.

Thank you.

DR. FULLERTON: Next, representing the American Feed Manufacturers Association, Lee Boyd.

REMARKS OF LEE BOYD, VICE PRESIDENT, AMERICAN FEED MANUFACTURERS ASSOCIATION

MR. BOYD: I am Lee Boyd, representing the American Feed Manufacturers Association, a national trade association which represents the manufacturers of livestock and poultry feeds.

The basic role of the industry that we represent is to supply the animal feeder, the swine feeder, with a package of nutrients. Our main business is blending the various ingredients into a formula feed producing this in volume. As part of being a service industry, we do include various animal drugs in our feeds to the extent that I believe some 60 to 80 percent of the animal feeds produced today contain at least one animal drug.

I am sorry, I can't tell you what the percentage of hog feeds is that contains sulfa methozine.

We are subject to various regulatory controls. Probably the most comprehensive are the good manufacturing practice regulations which FDA publishes. These have been, in effect, their original version for some 10 years, a later revised version for the last 2 years or a total of about 12 years.

Those regulations require that our industry take all appropriate reasonable steps to insure that we have the right drug at the right level in the right feed and that this feed is labeled with the appropriate feeding directions including, of course, the most important direction of all, probably, the withdrawal period.

On the other side of the coin, we must also take all reasonable, feasible, measures to preclude contamination of nonmedicated feed or other medicated feed with a specific animal drug use in the production of one's need.

There were some comments made earlier about some residual material left in the system. I think common sense and logic will tell us when you are dealing with a feed manufacturing plant that is producing tons and tons of feed a day that there will be some residual left in the system. The basic way that we have of handling that, frankly, is sequencing our production of medicated feeds, grouping to the extent possible the same medication, the same medicated feeds, so they are all produced one after another and following that with a nonmedicated feed, usually for the same species or species that is compatible with the drug.

And in addition, that is refined to the point where we try to produce a concentrate-type feed, at that time, which will be further diluted before it is fed. I might mention it was by common sense that we went into this type of a program because the analytical method would not tell us whether there were any animal drugs present. We did this through a common sense approach originally. If there is any trace of the drug left in the system it is directed to an area where it cannot conceivably create any problems.

We recognize that there is a problem here with respect to the sulfamethazine residues. You have heard a lot about it today.

We are thankful we are invited to be part of the program. We would like to be part of the solution also.

As Dr. Pruitt has expressed for the Animal Health Institute, the Feed Manufacturing Industry, American Feed Manufacturing Association, stands ready to help in any way it can.

I should point out, too, that we have one customer for our feed, and that is the animal feeder, and we are vitally interested in his welfare.

Thank you.

DR. FULLERTON: Thank you, Lee.

Next on the agenda is Dr. William Speck, Associate Professor of Pediatrics, Case Western Reserve University.

REMARKS OF DR. WILLIAM SPECK, ASSOCIATE PROFESSOR OF PEDIATRICS, CASE WESTERN RESERVE UNIVERSITY

DR. SPECK: Thank you very much. In terms of a little background information, I am an Associate Professor of Pediatrics and Microbiology and Medicine at Case Western Reserve University in Cleveland, Ohio. I am

a primary care physician. I am not a laboratory-based physician and in my sub-specialty practice of infectious diseases for the past 8 to 10 years, my primary responsibility has been caring for infant children and adults with infectious diseases significant enough to require hospitalization.

It was over this period of time that I have gained a certain amount of expertise in the use and abuse of the antibiotic in the sulfonamides class.

What I thought I would do today is address myself to some areas of medical concern that arise after finding detectable levels of sulfonamides in animal tissue.

One concern relates to the potential for the emergence of multiple drug-resistant bacteria in the exposed human population. The second concern relates to the toxic side effects inherent in sulfonamide administration. The concern relating to the emergence of bacteria with multiple drug-resistance is based on the observation that the widespread use of antibiotic supplementation in animals feeds results in the emergence of bacteria in the treated animal population which possess patterns of multiple drug-resistance. Of particular importance in this regard are the enterobacteriaceae which possess transmissible multiple drug-resistance mediated by episomes known as resistant transfer factors (R-factors).

Since such drug-resistance may be transferred from one gram-negative organism to another by the process of conjugation, levels of drug-resistance may accumulate in the normal nonpathogenic enteric flora under the pressure of long-term antibiotic administrations. These drug-resistance patterns can then be transferred from the nonpathogenic enterobacteriaceae to pathogenic enterobacteriaceae.

R-factor mediated multiple drug resistance patterns can thus be transferred within a species or between a species. This potential public health hazard; i.e., the emergence of multiple drug resistance bacteria in human populations exposed to low dose sulfonamides seems remote for several reasons.

(1) All of the sulfonamides except three (sulfaguanidine, succinylsulfathiazole, and phthalysulphathiazole) are rapidly absorbed in the proximal small intestine--a region of the gastrointestinal tract not normally inhabited by microorganisms. Thus, inhabition of bacterial growth at the levels of drug discussed today with preferential selection of resistant strains would seem unlikely.

(2) Moreover the low concentrations of sulfonamide which might conceivably reach the microbial population of the large intestine would immediately be inactivated by a number of intestinal constituents; i.e., dietary proteins, paramino benzoic acid, etc. Thus, any sulfonamide

which avoided the proximal small bowel absorption and reached the enteric flora in the large intestines would almost certainly be inactivated in the large intestine, and therefore, have no selective effect on the intestinal microbial population.

The sulfonamides are potentially dangerous drugs. The untoward effects that develop are numerous and varied and include nearly every organ system, OFBM in multiple fashion. An untoward reaction increases the likelihood of a severe response following subsequent administration overall incident of reactions about 5 percent.

The second potential public health concern relating to exposure of a human population to low concentrations of sulfonamides for extended periods of time relates to the toxicity inherent in this class of antimicrobial agents. Two forms of toxicity exist-the dose related toxic side effects and idiosyncratic nondose related toxic drug reactions. Dose related side-effects of sulfonamides are numerous and include gastrointestinal abnormalities such as nausea, vomiting, and diarrhea and central nervous system abnormalities such as headache and dizziness.

Renal and hepatic abnormalities have been described; however, they are extremely uncommon. Toxicities of special concern are the blood dyscrasias which have been associated with sulfonamide administration which, although extremely rare, are associated with significant morbidity and occasional mortality. These dose-related toxicities would seem unlikely to occur in the population being discussed today, since the quantity of sulfonamides consumed would be considerably less than that utilized therapeutically.

However, no information is available on the chronic long-term effects and potential chronic toxicity of sulfonamides. Patients on sulfonamide proploylaxes for extended periods of time do develop drug reactions but whether these are related to chronic administration with accumulation of sulfonamides or the dose being administered remains to be determined. Thus the theoretical possibility does exist that long-term administration of low dose sulfonamides might lead to drug accumulation and toxicity.

The idiosyncratic toxicity of sulfonamides are much more common than the dose-related toxic manifestations associated with sulfonamide administration and may be important in today's discussions. These idiosyncratic reactions generally manifest themselves as skin rashes which take the form of a maculopapular or an urticarial rash. However, erythema nodosum, exfoliative dermatitis, erythema multiforme, and the Stevens Johnson syndrome may occasionally occur. These cutaneous abnormalities may be accompanied by a "serum sickness-like illness" with fever and joint pain. Additional idiosyncratic reactions include hemolytic anemia, granuiocytopenia.

These idiosyncratic reactions of sulfonamides are not drug related to drug-dose or to duration of therapy and may occur following a single

dose of the drug in question. More importantly these toxic effects represent hypersensitivity phenomenon, and thus individuals previously sensitized or allergic to sulfonamides; i.e., during treatment of a urinary tract infection on reexposure to sulfonamides even in miniscule quantities, might respond with one or more of the aforementioned idiosyncratic reactions. These idiosyncratic reactions, especially in individuals previously sensitized to sulfonamides, might represent a significant public health hazard in our population.

In summary, the public health risks of low dose and chronic sulfonamide administration are theoretical and relate to potential acute and chronic toxic drug reactions. Insufficient information is available at the present time to accurately define the risk to the exposed population. Thank you.

DR. FULLERTON: Thank you, Dr. Speck.

That concludes the formal presentations. We will now open up for a general discussion. Those in the audience may participate by either making statements or asking questions. I will remind you again that we have in the audience two people who will hand you a microphone and recognize you so you do not have to stumble over feet to get to a microphone.

MR. KEATING: Al Keating, I am Director of the Livestock Department of the American Farm Bureau Federation.

For those who may not know, the American Farm Bureau Federation is a general farm organization with affiliated State farm bureaus in 49 States and Puerto Rico.

Most swine producers are members of the Farm Bureau.

We are concerned also on this matter. Farm Bureau members recognize the importance of retaining sulfa drugs for use in animal feed; we have seven persons here today, some of which are swine producers, which expresses our true concern.

We have had considerable involvement. I just want to make a very brief statement here on this issue. Particularly during the past year, the AFBF Swine Advisory Committee, which is made up of a maximum of 20 swine producers from major production States, at a meeting early in 1977 discussed this matter at length and recommended to our Board of Directors that we come up with an educational program to go to the swine industry to suggest that swine producers closely adhere to withdrawal periods, cleaning of feed-handling equipment, working with feed companies, and so forth.

We have consulted with the USDA meat inspection and FDA; we have worked with Dr. Van Houweling, and we have another briefing session coming up in

February which we are hopeful Dr. Van Houweling will be with us at. We are currently carrying out an educational program across the United States, hopefully in most of the 49 States and Puerto Rico. We are putting out, as are many State farm bureaus, news releases and brochures on the issues. We are suggesting that our county farm bureaus call meetings involving feed companies, veterinarians, and county agents to get at the problem, to encourage withdrawal periods and cleaning up of feed-handling equipment.

I just point this out that we are trying to get to the producers to help reduce this residue problem.

In listening to the discussion, just two more points occurred to me here today. We also want to be sure that the scientific facts show that there is a problem with respect to the further use of sulfas by humans. I do not believe that this has been adequately covered here today, except perhaps by the last speaker, Dr. Speck. I noticed in many of his remarks he said may or might, which is very good scientific terminology, but I think we need to explore this further.

Another point that was brought up related to swine identification. Our current position organizationally on swine identification is that it must be tied to the disease eradication and indemnification program where it is needed.

We have other producers that are here, and they may want to add to what I did say here at this time.

DR. FULLERTON: Thank you, Mr. Keating.

MR. SHINHOLZ. My name is Howard Shinholz. I am from Lee County, Illinois. I share the same problems some of these hog producers expressed here a little bit ago.

On June 10, 1977, we had a load of hogs sent up to Swift & Company, and on June 28 I was notified that they found sulfa residue in the liver and muscle. We checked around to see what we could do to get this cleaned up and were told to clean our lots with the next bunch of hogs we put in. We were very careful; we did not feed them any sulfa, and we kept our lots as clean as possible. I was told in order to clear this up I would have to shift the five hogs, like the other gentlemen have here. So on November 8 we sent five hogs back up to Swift, and on November 29 we were advised our hogs were in compliance. So on November 30 I shipped up 83 more hogs to Swift thinking that I was all cleaned up.

I guess it was on December 27 I received another certified letter from the Department that said they had found .15 parts sulfa in the liver, but the muscle had zero point in it.

So on January 5 I sent another five hogs up to Swift again, and to this day we have not heard from them where we stand right now. But it gets pretty old when we have to do this.

I might add that Swift paid us about two-thirds of the value of those five hogs, so it cost us some money on that.

What I guess I would like to ask here today, it has been discussed, is how accurate are the tests, how accurate is the identification of samples sent in? I asked the veterinarian up at Swift's how they handle it. We took those hogs in a week ago last Wednesday. He said they possibly would not be slaughtered until Thursday morning, and the samples would be frozen and not sent to Kansas City until this past Monday morning, a week ago today.

Now, I wonder how accurate the tests are and how accurate the samples are kept apart and, gentlemen, I guess this is my problem. If you have any questions I will try to answer them.

DR. FULLERTON: I believe you had a couple of questions there, didn't you? Do you want me to put someone on the spot here and have them answer your questions?

MR. SHINHOLZ: Pardon?

DR. FULLERTON: You asked a couple of questions. Would you like me to put some of these people up here on the spot so you can answer yourself?

MR. SHINHOLZ: If you please.

DR. FULLERTON: Dr. Spaulding.

DR. SPAULDING: Okay, as I have explained before, the accuracy of the test is as good as current analytical methodology allows us to be. If you want more specific answers as to the conduct of the tests and more technical information, I will refer you to Tony Malinoski who is in charge of our analytical methods and verifiability of it from a quality assurance within our laboratories, and so if you want he can get technical. If you want to get down technical as to the accuracy of the test and how it compares with other methods of measurement.

MR. MALINOSKI: The actual reproducibility of sulfa analysis is as good as any other residue procedure. We generally work with a standard deviation of about 15 to 18 percent, and this is probably one of the shortcomings of attempting to enforce the tolerance at .1 or below because of the verifiability of the procedure. In particular, in the values from our Kansas City laboratory, we have a very good chemist in charge there; he has been accumulating data, not only on the Tischler procedure but also on GLC procedures.

We do not have data with us today, but we can get you a copy of the last tabulation we had from our Kansas City laboratory. In general, whenever we speak about reproducibility within a laboratory, we are generally about two-thirds below an intralaboratory study so that the variation from our Kansas City laboratory is in the order of 10 to 12 percent for a single standard deviation. If they want that, if they would send a letter to us, actually to Dr. Spaulding, we will see that they get a copy of that tabulation.

MR. SHINHOLZ: Another one of my questions was on the proper identification. As I told you, I talked to the veterinarian at Swift & Company on the way this is handled; one fellow said livers were thrown on the tray all together, and I really wonder about the proper identification of these five hogs. We opened the gate and took out five hogs. As soon as that was cleared we shipped the other 83; they picked one hog out of this load, and I got what I call ---

MR. MALINOSKI: That is one question that I will pass the buck on. In particular, I will have to refer to Dr. Berry on that because we have to work on the assumption that whatever sample we get has been taken properly, but we also essentially have to take or remember that there can be misidentification. We have seen it. When we do not get liver or muscle tissues that agree ---

DR. BERRY: I could only answer, of course, all of our testing would be for nil of there was not proper concern for identification.

On the five hog samples I think you are talking about we stress in the plant, particularly the identification of those five hogs, because it really is the first real check on the violation or extent of the violation.

I do not know much else I could say unless I say ---

MR. MALINOSKI: May I add something to that? There is one other check we use, one other thing we have to depend on as a regulatory chemist, is data we generate must fit a general pattern. If it is muscle tissue, muscle and liver tissue do not fit this pattern; normally our results are essentially put down as unidentified, and if we find a level of liver we also have to find one in muscle tissue at approximately somewhere in the two-thirds of that value. If this is not true, it is something that we are not essentially using in the patterns because regulatory chemists essentially have to not only look at analysis that they are doing, but it must be an evaluation and must be done in the light of everything we know about the drug itself.

MR. SHINHOLZ: Did I understand you to say if you find it in the liver you should find it in the muscle also?

MR. MALINOSKI: Generally speaking, not always.

When we essentially report ND, it should not be zero; it is something we do not report anything below .05. Anything below .05 in our laboratory is reported zero. We have no confidence below .05; it should have been ND--we say on the average. The other fact is that this is a single sample, and when we say average you are taking count of the variation of procedures in both liver and muscle; it throws them a way out. You have to look not at a single value but what is occurring or what is the pattern that says liver sample .15. If they are reporting no higher than normal on that true value of 1.13 or somewhere in this range, and our muscle tissue sample, it could be lower--.05 is not too far out.

DR. LLOYD: I would like to ask a question of Mr. Malinoski.

Assuming Bratton-Marshall positive tissue, .01 per part, what would be the coefficient variation of other nonidentifiable, primary amines ---

MR. MALINOSKI: I do not have any value on that. We had a problem with the Tischler procedure initially and about 1973 is when we started working on GLC and thin layer procedures to essentially identify the procedure.

When I speak as a regulatory chemist I am saying I cannot take as official procedures Tischler if I do not have additional confirmation that it is correct. We have not had an opportunity to look at false positives, but we do have a fairly good correlation that we will identify GLC, which is more specific than the Bratton-Marshall and Tischler and it is very good.

The false positive has always bothered us.

DR. LLOYD: I agree with that but I still use the Tischler for the final quantification ---

MR. MALINOSKI: Yes, sir, but that final quantification must agree with GLC in the most part. It is something when I say that we essentially, the philosophy of residue analysis is such from a regulatory point of view we cannot leave ourselves open to question. We use every technique we have available to assure ourselves that it is positive.

There is one area that is extremely difficult to occur. What we are talking about is the number of essential samples that must be analyzed before any particular analyst is truly a qualified competent residue chemist. This is an area that no one can get any figures on, and it is a problem in the earlier years in particular when we suffered because we were reporting a high number of false positives. This has given the Tischler analytic procedure such a bad name.

The Tischler procedure by itself is not bad; it is how it is interpreted and how it is used. We have a general background of Tischler in our swine

where we are essentially, if you look at all samples, about somewhere three parts per million of sulfa.

DR. SPAULDING: There is a factor in these swine muscle samples and swine liver samples, that is, if you take laboratories' experimental conditions they usually give you a very clear and definite ratio. When you are dealing with field samples and when you are dealing with the facts that have been brought up by the researchers, which stated that the swine can pick up violative levels by inhalation, this is what they are talking about in reality when they talk about breeding out of the environment. When you find the swine in fact can pick up by ingestion both slightly contaminated feed and the manure pack, then all at once these withdrawal data start to fall apart as to exact ratios. So on a single hog you cannot make definite statements; you can look at the overall pattern. As you say, when a single sample falls out of this general pattern, we take special precautions to see that the result that is reported is as accurate as science will allow us to make it.

MR. MALINOSKI: When we get something this far out we also suspect interchange of sample. We hope they came from the same lot of hogs.

MR. GARNER: We are talking about something you say you cannot prove your system by one hog, but you have nailed an individual businessman to the wall with one hog. This is a concern of the industry, and I feel that our earlier recommendations that there must be some kind of a committee appointed representative of those involved to study this in greater depth before we go any further in tearing an industry apart, and we are tearing it apart on "if's", "maybe", and "variables" except as far as the industry producer is concerned. This is one of the great emotional things that is happening in our industry today.

I do not think any of these people delight in dealing in these emotional attitudes or platitudes, but I cannot fathom how we can defend our system by averages and variables and yet we nailed the producer to within a hundredth of a point. This is what is of great concern.

DR. SPAULDING: Marvin, as you know, we are willing to work and discuss this problem whenever you like with you and your group. That is no problem from a discussion standpoint.

In answer to your specific question, as you know our law requires that we protect the consumer. Furthermore, I understand the system by which drugs are approved. If this system was perfect we would never find violations because the tolerances are established above the fact where we expect to find any drug residues in violation.

Now, the question then comes back, what about the single producer? The thing is that on this one sample about which everybody is quite disturbed is that if we do take action because we have administrative proof

that there may be a system of management that is in fact out of compliance, we have got to face the consumers on the one hand. Can we very well say to the consumers we have reason to believe this man may be selling you hogs that will be harmful to your health, but we have got to prove it so we will let him continue to sell hogs until we prove it beyond any scientific doubt.

Can we do that?

That is one question.

The other side of the question is what we need to do. Do we take more samples from that producer? If he was in fact producing hogs in compliance, from these five samples it would show is that he was in fact. Remember, there is 85 to 90 percent of the hogs coming to market today which meet these criteria and that are in compliance. As I said, it would be far easier for me to explain a much higher violation rate than to explain why we have 85 to 90 percent in compliance hogs coming to market today.

MR. CLAYTON KINGSTON: When you talked to the gentlemen from Illinois who took his hogs to Swift, when he took his five hogs they took muscle, liver, and kidney. They did it on the first hog. The next time he sold hogs he had to let them know he was selling hogs. At that time they only took a liver sample. So his liver was positive. He did not have any muscle sample.

MR. LOGAN: Clayton, you might also comment to the fact that we need to be informed. Dr. Berry, I thought you must have mentioned this. You do not throw five livers up on the table; those pans are moved and specifically identified to that individually identified carcass as well.

DR. SPECK: As an outsider I was kind of curious if anybody in the animal food industry has looked at the efficacy or growth promoting properties of nonabsorbable sulfonamides? Certainly if one is worried about tissue levels and serum levels, if that really is a factor, if anyone has looked at it? It seems to me a fairly simple thing to look at.

DR. VAN HOUWELING: I said I am probably one of the least qualified to answer the question, but, Dr. Speck, I think the swine farmers' primary concern is to have a drug for atrophic rhinitis.

DR. LLOYD: I would like to address a question to Dr. Speck. I have seen the sensitivity that you described, having been a corpsman in the Navy, and there were some horrendous scenes. I saw a couple of kids with skins dropping off. But I wonder what level you would estimate that you would have to give to a human being to elicit this reaction?

I have done some calculations here. Assuming a tenth of a part per million in food, which is one-tenth of a millimeter a gram per kilogram, and giving a safety factor of 0 to 100, that means give a dose of .05 milligrams, to a kilogram of man, would you say that dosage would elicit a hypersensitivity?

DR. SPECK: As I am sure you well know, idiosyncratic reactions are not dose dependent. I think once an individual has a sensitivity response to sulfonamides it is usually when they are being administered for a dose therapeutic indication. I do not think anybody knows the minimal amount of sulfonamides that will then induce a subsequent hypersensitivity rash on that individual. You could never do the study.

The reason I said maybe and perhaps is what you would have to do is take a population of 100 individuals, who had developed hypersensitivity reaction to sulfonamides at usual dose and titrate them to see at what blood level and what tissue level they developed recurrences or subsequent hypersensitivity reactions. It might be that at the level we are talking about they are not significant.

I think with the state of the art the way it is now in terms of human investigation, unfortunately nobody could ever answer that question. We have seen and have patients who have had acute antiploylaxes on drugs like penicillin if they consume a dairy product. For example, with residual levels of pencillin they will again have a reaction. It probably varies from individual to individual. That is the reason I said maybe and perhaps. You cannot do the study. Who had a sibling, spouse, or infant who had had a reaction to sulfonamides would want to do that kind of study in order to find out. We are talking about a small population. Five percent of the individuals treated with therapeutic doses for an appropriate period of time on sulfonamide develop a reaction.

Of that 5 percent, probably less than 5, maybe even less than 3 percent have idiosyncratic type of reaction. If that happens to be you or a member of the family, statistics do not mean very much. I do not really know the answer to this question.

DR. LLOYD: Even a hypersensitivity has a dose response relationship, has zero at the lower end.

DR. SPECK: Right, you are right, no drug, no reaction.

DR. LLOYD: What is no drug, that is my question:

DR. SPECK: Well, I am not saying that the results that individual's getting or quoting are significant or insignificant. I am assuming for the purpose of my discussion if there are detectable levels of sulfonamides all the inherent limitations in the test--but assuming, I assume for the purpose of my discussion that there were detectable levels of

sulfonamides. Whether or not they are or not, I hope there are other individuals to answer that question who are more expert than I in determining sulfonamides.

My statement was made on the assumption there were detectable levels.

Once again one could not do the test. You could take sulfonamides, you could take pork or pork products that had "detectable levels of some sulfonamides" and you could feed them to individuals who had previously demonstrated hypersensitivity phenomena and use a human as you say, but nobody would tolerate that.

I was assuming there were levels. I grant you I do not know enough. There is something inherent in it. Bratton-Marshall you mentioned. I am not an expert on chromatography, I am simply a physician.

MR. ROSENDALE: Virgil Rosendale, President of the National Pork Producers Council. I am really not interested at this point in shutting down this very excellent discussion.

First of all, I would like to thank the people involved for establishing a meeting of this kind for today.

Secondly, I think it should be quite clear that we have a problem. Dr. Spaulding in his statement this morning indicated that he felt that with the cooperation of the producers and the cooperation of his department we could arrive at a solution. However, I would hasten to add that I think that group needs to be broadened. I think the testimony of Marvin Garner spoke very well to that.

I think, further, we need to conduct additional research to assure that we do know the best management practices that a producer must apply. There certainly are at this time some indications, I think, this thing needs to be tested further.

Secondly, it has been proposed this afternoon that as an additional solution we adopt or that you adopt the matter of massive mandatory identification.

The National Pork Producers Council certainly is in full support of the 100 percent identification of sows, boars, and stags tied to a disease eradication program.

In regard to the massive identification of all hogs, this has some long-range implications. This has implications of umbrellaing in many, many activities that can be generated, and it is my concern and it is pertinent to the producers to support this program before this kind of activity is initiated. I think there needs to be a cost-risk benefit study conducted. I think this is very important not only for the

producer but also for the consumer, because they are the ones who pay the price.

As I said earlier, we have a problem. The solution to that problem lies with the people that represent the industry.

Thank you.

MR. SHARP: Roy Sharp, a producer from California.

I might mention in response to Virgil's point that total identification in hogs, if you were to use the round number of 8 million head marketed during a year, even at the estimated cost by marketing agencies of 15 cent a head comes to $1,200,000, just for identification each year.

If I understood the figures earlier this morning, there were only 12 hogs out of the testing program that were not identified, which came to something like 4 percent. That seems like a terrific cost to try to identify 4 percent of what is not identifiable. In our area almost all hogs by any packing company are identified in one way or another when they go to slaughter.

They know who brings those hogs in.

DR. FULLERTON: We have heard everything from 96 to 60 percent identifiable out there today. I do not know what the figure is. They have come from several sources and there are several arguments on that, so I really do not think we know today. That may be one of our problems.

MR. SHARP: I would like to take just a minute of our time. We are here today to express opinions and facts concerning sulfa drug residue in meat animals. I say opinions because our Federal Government too often operates on and reacts to opinions. I say facts because legitimate and reasonable interpretation of facts should be the guideline for our Government, especially that part of Government that tries to regulate agriculture. Agriculture is only one part of our great America, but what a part. America is without a doubt the greatest country, people, government, way of life this world has ever known.

Production is what made America what is is. Agriculture is for all production in this country. It produces the best in abundance for not only our people but for much of the rest of the world.

It is also one of the biggest users of other products in this country. It supports millions of related jobs and people. It does not affect a few segments of our country, it affects every single living individual. Because you have to eat to live. American agriculture has produced the most, and the healthiest, and the most varied diet in the world, and at the least relative cost for the consumer.

Now what are we trying to do, you the agencies of our Government, the representatives of the people? You are telling me that if the portion of food they produce has a trace of a substance called sulfa, I cannot sell my product until it no longer has this trace.

What is sulfa? It is a chemical used in combating serious infections in both man and animals. It is not a poison, it is a growth inhibitor of certain bacteria so that natural white blood vessels can normally overcome infection. It is used in some food production to prevent disease and produce a healthier product for less cost to the consumer.

If this sulfa product or any product showed reasonable danger to the consuming public our industry would not use it. If it showed a tendency to produce resistance bacteria it would not be used, and that is still a theory. It has been used as other medicines have been used in the livestock industry for over 25 years without any proof of developing resistant strains in humans.

How do you know sulfa is in the food product? Today we have machines capable of identifying certain products in such minute quantity. Can you imagine tracing something to 1 part per billion or trillion? They can do this. A billion is almost incomprehensible to most people, even when it comes to dollars spent by legislators.

The law that decides whether something is in violation regarding tolerances and FDA regulations is the Delaney Amendment. It does not take into consideration the reasonable or intelligent approaches as far as our industry is concerned. It did not anticipate the technology that has been developed for identifying substances. These agencies of the Government that are charged with carrying out the law need to also help determine how the law is interpreted and how it is administered.

That is their moral responsibility to the public, our industry, and to themselves. To use and follow regulations that are not fair and reasonable has to stop when the testing becomes so sophisticated in such small quantities that the chance of error gets larger because of the contaminants. We have sulfa tests showing sulfa contamination in corn and fresh soybean meal where there is no sulfa present, but it is in violation of the law. You will tell me this is what the law requires. I would like to tell you that you are the people who have greater contact and greater knowledge than most of us. You need to help us. If the regulations are not right, help us to help you make them reasonable and fair.

I am told that the Delaney Amendment cannot be changed. Hogwash. It was put in by people, and it can be changed by more informed people. Our legislators do not want to be against motherhood, apple pie and good health, and such things. They are good people who want to do the right thing. In order to do that they need help from people like you who are in these responsible agencies.

Please help us with your guidance to continue good health and progressive agriculture. We do not try to use your offices, so please do not try to use your offices and positions to make a show of law enforcement and acceptance of unreasonable regulations when it can destroy us, the producers, and the job we are trying to do.

There has to be a point that is reasonable for determining when a product might have a possible detrimental effect. There also has to be a cost-benefit appraisal made in some areas so that restrictions will not hurt our people more than they might help them. I beg of you to use the advice of knowledgeable people in our industry and through the universities who know both sides of this problem. Too many times in the last few years, small groups of loudly heard people have put forth ideas and demands all out of proportion to the people they claim to represent.

They play on publicity and news media sensationalism.

I would close with an example of the lack of credibility we are dealing with when it comes to research tolerances and protection. In the diethylstilbestrol problem the relationship of amount found in beef liver compared to the amount used to produce cancer in laboratory animals, which incidentally are bred specifically for susceptibility, a person would have to eat 4,000 pounds of liver in one day to equal the dosage used to produce cancer in the laboratory animal. Cooking would have prevented the possibility.

Is this the way our people need to be protected? I don't think so. The regulatory agencies need to look at these problems more thoroughly and realistically before trying to regulate. Our industry must regulate the use of all products but in a reasonable way that will produce a healthy product at a low cost to the consumer. We do now and hope we can continue to do so in the future without too many Government hobbles.

Thank you.

MR. LOGAN: I would like to comment on the remarks by Mr. Sharp.

First of all, the percentage of animals that are identified, and we have been wrestling with numbers most of the day, and Dr. Berry and I were looking at one of the reports here recently that do show some level and degree of confusion. I cannot, however, very confidently tell you that there is one major packer sitting in this room that identified 100 percent of his hogs. There is another one in the room who identifies 70 percent of his hogs. And I am looking at the sampling that is put out by Dr. Trabosh's agency, on 7,122 samples, approximately 76 percent of the animals, so 60 to 70 percent levels seems to me to strike a much higher degree of accuracy than the figure we heard this morning.

Secondly, it also points out to me the application of the thesis or arguments we put forth that of these 7,122 samples, 5,185 were drawn from producers that could be identified, and this is the area of our concern, and that in the last analysis drawn on November 30 after the pressure had begun to generate in October and November, that the market sample violations almost doubled, which does establish the concern of ours. And second, the point you made of the cost of 15 cents per head, we have heard this number over and over, and frankly it borders on the ridiculous. It does not cost anywhere near that.

DR. FULLERTON: Are there any more questions?

MR. LEE: You made what I thought was a very serious statement in your presentation. You said that some people were advertising that they bring the hogs to me, I don't identify. Would you like to elaborate on that a little bit further?

MR. LOGAN: If you are around the livestock industry to any great degree, and I did not know what your particular field of endeavor is, and sometimes some of us in the packing industry wonder if we are in the right business, just as you as producers do, you are well aware of the fact that you can hear many, many things and you can be advised of many, many things that never show up in black and white.

Yes, there are areas who have indicated to the best of our knowledge and best of our discernment in the animals that are brought to their particular, and we have no quarrel with where people market their hogs, that is their business--but we do particularly feel that as sensitive as this total area is, that is a difficult way to achieve a level of business. We think it is the wrong way to go about it, and we do hear that it takes place.

Clayton, I think could you enlarge upon that?

MR. KINGSTON: No, Ralph, I think you have said it very well.

MR. LEE: What do you call advertising? You are just saying word of mouth.

MR. LOGAN: I am saying that is primarily what we hear. I can only say this. In addition I would not begin to attempt to speak for some of the others in the industry. Some of the others in the industry that we have communication with indicate that they have picked up even a more definitive degree of advertising than that. I can not personally put my hand on it, no. I do not know whether that answers your question to your satisfaction or not. Believe me there is a very, very good grapevine in the industry.

MR. SHARP: Not to belabor the point, but using your figure of $50 for identification, if a man has 10 sows and markets 120 pigs during the year, that comes out to 40 cents a head right there.

MR. LOGAN: I think you are identifying the source of identification at the farm as opposed to a buying area, and that is what we are talking about, at the last point of transfer of purchase.

MR. SHARP: I was trying to come back and look at it from your standpoint.

If the marketing agency were the people who have to do it use the 15 cent figure, I was trying to get away from the marketing agency and come back to the home ranch.

MR. LOGAN: Here again I think you might comment, too, though you are a little more eloquent, your use of adjective might be better here.

MR. KINGSTON: To move from California to Minnesota we would take them free for you. At that time towing out of first hand means that before they lose their identification of our farm so when you brought them to your first marketing place, Omaha, Nebraska--terminal, the buying station or dealer in the country or anywhere--they would be the ones that should do the towing. It does not cost 15 cents apiece.

MR. LOGAN: Hammer freeze them.

MR. KINGSTON: Farmers cannot identify hogs on a farm to our satisfaction. There is a certain technique involved. You have got to learn how to hit them, you have to be quick on your feet and have a good arm. Then you have another kettle of worms.

DR. GERRITS: My name is Roger Gerrits. I am with USDA.

John, in light of the situation here, are we going to have a chance for some response? Everybody has moved to the Washington scene to put some attention on this problem. Several people have made suggestions. Can you give the people who have asked those questions what they have suggested might be the response? I know we cannot give definitive answers but can you give them some idea in terms of the possibility of followup? I have heard several different people suggest they want to work together.

DR. SPAULDING: Roger, in answer to your question, it is obvious that my staff is responsible for that, and in fact will contact these people. Hopefully we will get some idea before they leave Washington today as to suitable alternatives, because I am in agreement that there is more involved here than just USDA and the pork producers. It is a multi-faceted problem, a little unusual in residues where you cannot put your

finger and make a nice simple straightforward answer. Correct this and all at once everything goes away.

There is complete agreement on that. We need to sit down and reason together, both respecting the other's problems.

So the answer to that from an educational standpoint of getting to the people that are in fact out there trying to do their best, as far as I am concerned that is 100 percent of the pork producers minus that outside edge that if they were told to do it right they would do it wrong just to show it could be done wrong--they always exist. But we do need to, and one of the groups that we cannot get to, from a regulatory standpoint, and the pork producers could get to it most accurately and the research community. And when I say research, I am talking about both Government and academic--I do not separate them--could tell us what have the producers of the 85 to 90 percent of the hogs been doing over the years that keep them in compliance. They must be doing some things right out there.

Quite frankly,I cannot separate from the three producers that we had speak here today. I would say that all three of them are excellent pork producers. What is the difference in their operations than these other 85 percent? I cannot get at it, I do not have the data, and it is too great a difference to say that it is luck. So we need more information, and it is got to come out of people that are producing hogs.

MR. DAMMANN: I would like to comment on some of the things you have addressed. I would not like to leave this room with the impression we are establishing sanctuaries for violative hogs. I do not believe that to be the case. Because, if there is anybody running to a nonidentified pasture it is because what he has heard that has happened to a reputable hog producer. He is not running to a sanctuary because he is delivering principally violative hogs.

DR. FULLERTON: I haven't had an opportunity to talk today, and I generally say something.

Several people keep leaving so I have to get something said before we go.

Really what we can conclude today is that we have been testing swine for sulfa violations for about 4 years, and we have had no remarkable reduction in the number of violations until we talked about this meeting and got someone's attention. I do not know whether that has had any bearing on it or not. At least we have seen something in the last month or so that has given an indication that that sulfa level has reduced.

We have heard today a great deal of discussion about whether or not that is really a sulfa drug worth finding or whether we found it in the right

hogs out there or not. If we do not have valid tests for sulfa out there we should not have an approved drug. Was that particular statement fairly accurate, Dr. Van Houweling?

DR. VAN HOUWELING: Yes, sir.

DR. FULLERTON: So I think we are going to have to accept that we have got a valid test for sulfa drugs. I think we are going to have to buy that 15 percent of swine are violative whether they belong to the particular producer or whether they belong to somebody else, and Dr. Berry cannot keep the samples straight. That is another issue, and he can work very hard on that to get it straightened out if that is in fact the truth. But we do have a problem out there. I do not think that we need to work along with the idea that we are going to wait and wait and set up some task forces to study this thing on into infinity.

We have heard from FDA their position over there. They are very concerned about raising a tolerance. I think we have gotten some answers out of this thing today, and I do not know; I think we would probably need to meet with the people very shortly and come up with some rational way to go. There is one group today that has been conspicuously absent. Do we have any consumer groups represented here today? Would anyone like to speak up for the poor consumer?

MR. SHARP: I am a consumer and I am one of the largest consumers.

DR. FULLERTON: That is terrific.

MR. SHARP: I am one of the largest consumers because I eat more of my product, and there is nobody who is more concerned than myself about the product that I eat. I think that is true with everybody involved here. All of you are consumers. Sometimes to let what is called consumer groups, a very small number dictate to us as producers, as regulatory agencies or legislators or whatever, has been a great fallacy here in the last few years. I am sorry that some other people are not here to hear that.

MR. PRATT: I am Charley Pratt with the National Livestock Producers in Denver. We are the federated headquarters for 15 regional livestock marketing cooperatives. I have about 350 livestock members. About half of them market hogs through our organization. There are two or three things I would like to say. We endorse what Marvin Garner is saying to you for the pork producers. This is the industry talking to you. I know we are dealing in if's, but's, and unknowns, but I think you need to get specific with them before you bankrupt these folks.

The next thing, I believe out of our own testimony, what is it, 90 consumers is due to sulfamethazine, is that correct?

DR. VAN HOUWELING: Sulfa, it is higher than that sulfamethazine.

DR. FULLERTON: If that is your problem why don't you bend?

DR. VAN HOUWELING: Ban it.

DR. FULLERTON: Yes, if that is your problem.

DR. VAN HOUWELING: We might be starting on that course. If you hog producers agree that is what we ought to do.

DR. FULLERTON: Is there some other substitute for it? What is the trade name for it?

DR. VAN HOUWELING: I will let somebody answer that. There are other sulfonamides but I guess that is one.

DR. FULLERTON: These are thoughts but we are asking for views from the industry. It runs in my mind, if 98 or 99 percent of your problem is identified to one sulfonamide, if your withdrawal dates are not proper why don't you withdraw it. We would not be opposed to total swine identification. You are chasing 8.3 percent of the nonviolators and that is 80 million hogs, not 8 million a year.

MR. SHARP: I just used the small figure.

MR. PRATT: We are looking at 10 to 12 million bucks a year to identify all these hogs. When you get down to Omaha, they have got 8,000 hogs that day; you are going to go from what is normally a 1- to 2-hour marketing process to a 3-day process. To try to at that time take 8,000 head of hogs. You have not even talked about the shrinkage to the producer, have not talked about additional bruises or damage to the producers, and these are all in dollars. You heard these fellows here today saying from $18-30,000 in cost, and they are still not home free yet.

I would say to you that what Marvin Garner said to you, and these hog boys listen at them; you are hearing it from the industry, and these are the guys that are taking the brunt of it. Do not legislate them out of business.

DR. RILEY: This is a followup on what he said about the sulfa problem. There is an alternative. I will put in a little plug for the company; It is food for thought. Our company does have an atrophic rhinitis vaccine which was developed by Sweitzer. We have many producers who have used it and used quite a few million doses of it within the last year. It has been available and they have taken sulfas out of their operations. They have reduced atrophic rhinitis significantly and they find it very, very effective. So, when you are talking about removing

sulfonamides, a vaccine is the only USDA-licensed product that the data is there to support it.

MR. KINGHAM: I am Bob Kingham from Omaha, Nebraska, representing the River Markets Group. This is a group of the largest midwestern stock terminals in the country, members being Sioux Falls, Sioux City, Omaha, St. Louis, Kansas, Chicago, and Joliet. I want to take this opportunity to endorse and support fully the efforts of Marvin Garner, Virgil Rosendale, the National Pork Producers' people, and I also want to reiterate and speak to the same question that Charley Pratt has talked to you about.

We certainly do not want any effort as worthwhile as the one that has been under discussion here today not to have the complete input of the people who are basic in the trade--the national pork producers' people.

There are some very definite drawbacks in this system of anything that might require national hog identification. Being in the business and selling upwards of 10 million hogs a year in our markets, we are very cognizant of all these problems and the difficulties. We do not want simple self-serving national hog identification to be tied to the efforts that are under consideration here today.

Again, let me say in behalf of our people we admonish you please to listen to the people who are responsible and responsive for our industry, such as Mr. Garner and his people.

MRS. BRAND: I am Mrs. Richard Brand, from Hopkins, Missouri. I am the wife of a pork producer. I am a consumer and a mother, and we eat what we produce. I want to feed my children good food just as I want the people who buy our meat to be healthy. We do not intend to sell anything that is not good food. Just remember what we are producing we feed to our own families, and we want it to be good.

MR. ROSENDALE: I would like to make this comment and am making the comment as a pork producer and not as a veterinarian and practitioner. I would like to address my comments particularly to Charley Pratt's comments regarding the ban of sulfamethazine.

As I came to the meeting I think I recognized that that was an alternative. Dr. Van Houweling, I would encourage you to proceed cautiously in that area because I think it might have the end result of eliminating the residue of sulfamethazine and creating a residue of an alternative sulfa product.

Secondly, while sulfamethazine is used primarily for the control of atrophic rhinitis, and I recognize there is a new vaccine, I understand effective, I think it is also important the pork producers have sufficient sulfas available in cases of flu and pneumonia outbreaks. In the

interest and in my assessment of the value of that product, I think that we must pursue an alternative solution--one of research, massive communication, and education. Then if we need to take additional steps, okay, but let us go the other route first, and I am convinced that the industry can solve that problem.

Thank you.

DR. VAN HOUWELING: If you remember what I said this morning, I would like to repeat it, that it seems to me the bottom line is can this product be used by swine producers and not have excessive levels of residue. I guess that excessive level is going to finally be defined by the FSQS because it is their responsibility to inspect their animals and put the stamp on the meat. When they say it is more than we can continue to tolerate, it is at that point that we will have to proceed to use patterns, probably that is the first step, but I think everybody that knows quite a little bit about this knows that may not do that. Limiting up to 50 pounds, up to 100 pounds, when mixing and grinding equipment is used in common for feed for all animals. We can hear what a little bit it takes in the way of contamination of so-called withdrawal feeds because the problem plus the disturbing news about the recycling from manure and urine. In the final analysis, I am not sure it is a product that can continue to be used unless there is a level of residue somewhat above what we might expect, and if that develops I think we have no choice.

You have heard the Bureau of Foods speak very positively about the fact they do not believe the tolerance can be raised and, if the tolerance cannot be raised, then I really do not think there is any choice but for the FDA to start to proceed to withdraw the approval.

MR. KENNEDY: I have a question I would like to direct to both Dr. Spaulding and Lee Boyd. In our case, I do not feel the withdrawal of sulfamethazine could have helped our situation in that we never fed it; we never ordered it. We have an operation that costs over $2 million, and sulfamethazine supposedly has never been used in it. We did retain feed samples going back a year. Those samples showed negative on two tests. On one test, using the TLC method, that did show positive at .7 parts per million, which according to the data presented today would probably be too low to show tissue levels. Our out-of-pocket costs were over $20,000. In our case, with a 5,000-head inventory, every week we farrow 400 pigs. Every week 400 pigs have to go out the door because there is not room for them when we back up for 2, 3, 4 weeks, or 2 months.

Our in-house costs are probably $30,000 to $40,000. In our case then, who is responsible? We later proved the pigs were negative; We went back and some of the original tissue samples were shown positive. When we ran these samples they did show negative on the tissue samples. In

our case then, who is responsible for our loss? Is it USDA? Did they make the mistake or is it our feed supplier? Should they reimburse us for our loss? We have never ordered sulfamethazine nor had any sulfa in any of our feed ration.

I would like comment perhaps by both of you individuals.

DR. BOYD: Mr. Kennedy, I believe the individual that is supplying your feed called me and reviewed his practices with me to see if they were in line with the industry norm and what we knew we could do in handling drugs in feed mills and they were. I think in essence you may have answered your own question because the method that you indicated, ultra-sensitive method .7. Dr. Bevill, from what you presented today, that would create no problem if there actually was a .7 level of sulfa there?

DR. BEVILL: I have not looked at .7. At 2 parts per million you have a problem. I think in many cases that the labelings of good, sensitive assay is one of our major problems as far as feed is concerned. Most of the methods currently used today will detect about 5 parts per million and no lower, which means that there are feeds which could be contaminated, declared sulfa-free and produce residues in swine.

DR. BOYD: I would agree we need a more sensitive method. We have got to work with what we have available and the procedures that we followed. Of course, as indicated in my comments, the feed industry is basically a service industry when it comes to medicated feeds, and we include the medication as a service because feed is the most logical, feasible route of getting the drug into the animal, particularly the prophylactic type drug--the most important disease prevention and control product which we need when we crowd animals together.

Fortunately, the Food and Drug Administration clears most of these products. There are a few older ones which we use under historical concepts, but the Food and Drug Administration asserts that these products are effective and that they are safe. And as I indicated, we are compelled to follow certain rules and regulations in the production of medicated feeds, which means that we do everything we can to insure that drugs containing feeds maintain their integrity and nondrugs-containing feeds maintain their integrity.

I do not know the answer to your question except everything I have seen would indicate the .78 would not create a problem if there was indeed .7 there.

MR. KENNEDY: My comment would be if we have about ten elevators in our area and we chose the one that does follow the best practices; they are careful. On the same sample of feed we did have split samples and it was negative, and another private laboratory called it positive at .7. Still, our costs were over $50,000.

Now, would you recommend to that feed manufacturer that he is responsible for your costs? We have never ordered medicated feeds or was it perhaps an error in sampling. This is our question. We are the producer and we are the one that pays the bill.

MR. BOYD: I can appreciate your predicament but then would hope in turn you can appreciate the feed manufacturers. He used a product in accordance with all directions and he labels it, et cetera. He is working with what he has available to him in the way of expertise. As Dr. Bevill indicated, we simply do not have ultrasensitive methods that would let us know what is what.

MR. KENNEDY: We have a good relationship with our feed supplier. We use over $3/4 million of feed. He told us if you put in your bill we will pay it; we will pay you that money. However, our insurance company will not stand behind it, and we sure do try to do a good job but they will not stand behind it because their legal advisers say USDA test is not an accurate number for them to pay that sum of money.

MR. BOYD: I will have to let John Spaulding answer that one.

DR. SPAULDING: What we are dealing with, it is quite obvious, Mr. Kennedy, you have a high volume, large volume, high dollar investment in your operation there. One of the things that we have as yet come across is a swine producer with an investment equivalent, greater or lesser than yours, that comes back to us and says that I am checking my own operation to determine that the changes that I make will not cause a residue problem, whichever it might be. Other industries have found this is a highly desirable and needed requirement in order to minimize problems. We have worked with these industries. They have worked out arrangements where they know where they are with a reasonable degree of assurance, but we lack this kind of data when we are getting down to the individual producers.

I remember I had a talk with not quite as big an operation but a producer that keeps 3,000 hogs on his farm. He does have to use sulfas, at least he intimated that he did. And I asked him, I said, where are you. He said, I do not know, and if I sent samples for you to test, if they are in violation you will have to come back and react as a regulatory program should. I said, how about sending the samples out, and he said no, that is a cost I am not used to; so $300 to $500 to know that I am in compliance is too much.

I cannot begin to say that I am going to tell you where your problem came from because I cannot, but we have reached a situation in the world today where we are all interdependent upon a system of production. Each individual facet of that production system must work to make sure the whole system works. The drug companies have a very vital stake in seeing that the procedures do not have problems. They distribute their products through feed mills.

When you talk about feed additives and feed mills, as Lee amply expressed it, our only customers are animal producers. They have an equal or greater stake than you do. You have a great stake in selling it to the packer, and the packer must you say he has to sell the animals so we get down to the consumer. So our program is intended to protect the consumer but do it in a way that we can feed back to the producer but in a knowledgeable way so the producer can make corrections. I agree with you, but we have problems. I am not about to tell you that my staff sitting here in Washington, talking on the telephone with many producers, going to producers' meetings that they are invited to--I am not about to tell you our inspectors, who are in the packing plants, they are not out in the field, can tell us very much about your problems, but at the same time when we started to put a real push on sulfa problems, why the answer that we got back is nobody knows. The pork producers that we met with, and these are people selected by the pork industry, we certainly did not go out in the open world, they came back and they looked at us and said the people are using these drugs carelessly.

This met with FDA findings on their farm investigations so we accepted that.

Then as additional data was gained, we started to believe there were other problems. FDA sponsored research. Mr. Garner mentioned the fact that when he asked if we would run the samples for him I told him no, that is right, because we cannot by law spend our money on research. If we opened our laboratories for every researcher that wanted some samples run, that would be the free and a most beneficial service to research and we would never meet the requirements of our own regulatory program.

You say why are you doing these samples now. The reason that we are doing them now, and Gene has not gone into the conditions of this test, you talk about putting the cards on the table, Gene has put his professional reputation on the table. We also have. We have joined him. Gene is sending these samples out before he knows what the results are. Talk to any researcher that will send samples out and says he treated these pigs this way, I am going to send them out before I get any results back. We asked that he specifically randomize and code these samples so that none of the laboratories involved would know anything about the history of treatment. If you think I am not going to have some mad chemists when you know there is a linearity requirement for accuracy, look at the results Dr. Bevill produced, and you will see that there are going to be some very mad chemists when they start working on those samples because they do not know how to adjust their instruments until they have gone through the TLC step. But this is the reason that we are doing these samples because there has been question about our analytic methodology and, quite frankly, what we have done is say we will accept that challenge, and we will bet our work will stand up with any other laboratory in the country.

We have already had a challenge by several different people, and it has stood up so we are not taking that much of a risk either, but we did not have this information. In order to resolve these problems, we can identify them, we can go to the producer groups and say, hey there is a problem. You all know when I made my talk this morning I mentioned four steps that we always go through, and the fourth step is we settle down and work together to resolve it because you have unique information we do not have. We have unique information about residue problems that you are not supposed to have. If you have it I welcome it because it will save many hours of explanation, but until we work together neither one of us are going to achieve the goals that we are after.

MR. DAMMANN: Who pays the prices? We go through these four steps when the data that Mr. Kennedy has presented, who pays the price so that we can arrive at step four?

DR. SPAULDING: Who pays the price for all research? It is the taxpayer; it is the consumer. Who pays the price for all production? It is the consumer because they buy the final product. You are an intermediary in the system of production. You hope by producing that you can stay above your costs. Yes, the answer is you pay it.

You noticed I also mentioned that we have dealt with residue problems with all other species under meat and poultry inspection in the past 6 years. Who pays the price? Those groups? And when I talk about those groups and species, I am talking about the individual producers. They always pay the price.

I ask you when you use sulfas do you ask about any problems? Did you look and say what problems am I getting into? Did you put in quality assurance programs so you know you will not have these problems? The answer, according to you, is I did not know I had to.

MR. DAMMANN: We have the feed samples.

DR. SPAULDING: As Tony said on individual samples you are talking about quality assurance, individual samples. In the morning you are coming to my office and we will go over your problem; I will point out the loop-holes in the sampling that you have, and I will point out the areas in which you have not checked. That is simply from a residue standpoint, it is probably not that simple from a production standpoint.

MR. SMITH: My name is Tom Smith, I am with the Community Nutrition Institute. I wanted to ask Dr. Van Houweling if any lifetime or three generation reproduction tests had been undertaken?

DR. VAN HOUWELING: Not that I am aware of, not for the sulfonamides.

MR. SMITH: Would you think that would be the first step in determining whether or not the allowed tolerance levels could be raised or not?

DR. VAN HOUWELING: I think the Bureau of Food has said if they had 2 years to study they would consider establishing a finite tolerance, something above 10 parts per million. It will take 2 or 3 years to get it.

MR. SMITH: I think we have to continue to evaluate our food system from a consumption standpoint and not a production standpoint. It is the consumer who ends up paying the prices of the product. This problem also should be resolved. In recent months increased interest has been shown, has the violation risen to or decreased to something like 7.6 percent, whereas in July it was 17 percent. Certain steps are going to be taken--perhaps universal registration of animals, perhaps greater methodology of cleaning stalls, and switching feed levels must be maintained.

DR. SPAULDING: We are not complaining because of analytical methodology in the laboratory.

MR. SMITH: It is not or will not--

DR. SPAULDING: It is not. Because we keep our chemists working what we theoretically call 100 percent workload. When we talk about a reduction, this means that as we reduce the samples we reduce the number of people doing the assays. We put them on other tasks. So the workload per analyst remains constant, and also they are using exactly the same methodology so I believe that together on that premise is wrong.

I am talking about violations. The .1 part per million is a tolerance. Dr. Farber, if you want to express any opinion on that.

DR. FARBER: Well, at this present moment the agency still considers that the .10 part per million is the tolerance level, and I do not see any change in that tolerance as far as I can see.

MR. SMITH: I quite understand. I thought I understood the only time that the level would be increased was if lifetime and three generation reproduction tests showed that higher levels were warranted, is that correct?

DR. FARBER: Just for clarification, there are two types of tolerances that are issued to a manufacturer for his product. There is negligible tolerance, which is the .1 part per million tolerance that we are talking about. This is based on 90-day studies on rats and dogs and also marriage to the analytical exhibit and form kinetics of the material in that particular animal. However, if the levels turn out to be higher than the .10 part per million, even after a suitable withdrawal period,

withdrawal period commence rate, to the proper pursuits of veterinary medicine in that animal, you are still stuck with one-tenth of a part per million. The company then has the option to go for finite tolerance which requires more extensive test procedures. A 2-year plus study in the rat, a lifetime study in the mouse, three generation production study of which the rat study may be a continuous, possibly a teratology study if it is perceived the drug comes from a known class of teratogenicity and, lastly, the 6-months to 1-year mutagenicity study. That is basically the finite tolerance package the agency requires at this present moment.

DR. VAN HOUWELING: I was asked this question last week, so I will ask some of the representatives of the drug manufacturers here why doesn't somebody undertake that study, Dr. Pruitt.

DR. PRUITT: Ladies and gentlemen, as you probably well know, we spend probably between 65 and 70 percent of our research dollars now on so-called defense research. These are the items that are already on the market, that have been out there and in use for many, many years, as has sulfamethazine, and they have become to some degree commodity items. People in Bulgaria and other places send in 1-pound packages of sulfamethazine made some kind of way and sold on the open market. It is at least a problem to test all of these products.

Now we may indeed embark upon the various studies that Dr. Farber has talked about for our product and that is not going to solve your problem with sulfamethazine. Probably if we have anything like 10 percent of the market, how about the other 90 percent? Are you going to test their products too? We may well engage in the 2-year study, two rodents, not a three generation study, a year or two years in doing. I do not think that that will solve your problem.

MR. EISENBERG: David Eisenberg. I just wanted to mention we have done a lot of work with feed carryover in mixing systems. One problem feed manufacturers run into when he runs drug assays, to see if the carryover is extremely variable and when you are planning tests you have to wait for extended periods of time to get results back, then it takes additional time to reformulate tests. I could mention that a couple of broiler producers have used our tracer to check their bins to see how well they are cleaning out, what hangup there might be in trucks and so on, this could be a useful tool. We have not marketed the pork industry. Maybe as a result of this we will.

MR. TILLEY: Ken Tilley, International Producers Livestock Association. I would like to make a comment about some of the remarks. Ralph Logan and I have known each other for many years, and knowing him I am sure he will not want to make a derogatory reflection on the legitimate reputable livestock marketing associations in this country.

He did state that markets were advertising the fact they were not identifying and could be used as refuge for hogs with the sulfa residue. Just so there will not be any accidental reflection on the legitimate reputable livestock marketing agents, I would like to have it go on the record that Interstate Producers Livestock Association, which is the largest cooperative livestock marketing association in this country, does not advertise; we do not permit our livestock buyers to advertise the fact that we do not identify animals in all of our markets.

I have talked to some of the other reputable marketing associations and they, too, have out directives that their buyer should not take particular--

MR. LOGAN: Obviously, I would be less than intelligent to sit here and open myself to the possibility of libel or slander or anything else, and at the same time I do not think any of us who are in the industry are naive. There are many ways to accomplish anything that we set out to do. And know your reputation well, Ken, and I am sure very honest in what you portray.

MR. FULLERTON: Any questions?

Looks like it is time to cut it off. If there are no more comments, we will adjourn the meeting.

(Whereupon at 4:15 p.m. the hearing was adjourned.)